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Food Drug Cosmetic Law JOURNAL

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THE EDITORIAL POLICY of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis, contributions and comments are invited.

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Latin-American Food Code.—In August 1964, the Latin-American Food Code Council published the Second Edition of the Latin-American Food Code. Chapter VI of this Code begins on page 421. It discussses the regulations covering meats and similar foods. Included in this category are fresh and canned meat, preserved meat and fish, eggs, sausage meat, sausages and related products, and fishery products. The rules governing slaughterhouses are also included. Chapters I-V, VII, X, XII, XIII, XVI, XVII and XVIII appeared in previous issues of this JOURNAL. The translation is by *Ann M. Wolf* of New York City.

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Administrative Inspection of Health Facilities as Unreasonable Searches.—*Dr. Maven J. Myers,* who is Assistant Professor of Pharmacy Administration at the Philadelphia College of Pharmacy and Science, discusses a problem raised by recent Court decisions which find that administrative inspections conducted without a warrant are unconstitutional. In the area of inspection of health facilities, where it is very difficult for an inspector to secure a warrant, does the right of the people to be safe from unreasonable searches take priority over the government's responsibility to protect public health? But possible alternatives which would allow an efficient enforcement of the drug laws would weaken the protection guaranteed by the fourth amendment. Dr. Myers' article begins on page 456.

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Food·Drug·Cosmetic Law Journal

A Quick Look at a Bad Decision

By WILLIAM R. PENDERGAST

Mr. Pendergast Is a Member of the Washington, D. C. Bar.

WHEN A COURT PUBLISHES what is generally believed to be a bad opinion, the legal community tends to dismiss it as being unimportant. But this attitude is shortsighted and ultimately dangerous. Inevitably silence and inaction become consent, a fact especially applicable to food and drug cases where, if a decision is allowed to go unnoticed for any length of time, Government briefs are sure to describe the decision as one which "has stood the test of time and remains unchallenged to this date."

Therefore, whenever we see a poor decision, a record should be made of the Court's errors in the hope of forestalling just such statements. The recent case of *United States v. Moore Drug Exchange, et al.*[1] is an outstanding example. For this decision is not only utterly wrong, but is also one which could have a wide impact on those industries subject to the Food, Drug and Cosmetic Act.

In *Moore* the Court held that the protection of the guaranty law of the Food, Drug and Cosmetic Act extends solely to retailers and that, therefore, the Food and Drug Administration (FDA) guaranties given to manufacturers, wholesalers, or jobbers are worthless. The function of such FDA guaranties has always been generally understood as that of relieving those who deal in foods and drugs from criminal responsibility if they hold such a guaranty from the person who shipped the food or drug to them, if they act in "good faith," and if they cooperate with FDA in supplying them with relevant shipping data about the product. This guaranty protection applies so long as

[1] *United States v. H. L. Moore Drug Exchange, et al.*, CCH FOOD DRUG COSMETIC LAW REPORTS, ¶ 40,191, 239 F. Supp. 256 (DC Conn., 1965).

the person holding the product does not in any way alter the product or its labeling. It is therefore surprising to find a District Court holding that guaranty protection actually applies only to retailers.

The principal defendant in *Moore* was a wholesale drug house charged with introducing an adulterated and misbranded drug into interstate commerce. The defendant had moved to dismiss the charges, alleging that it was immune from prosecution in this case because it had complied with the guaranty provision. It was conceded by all parties that the wholesaler had received the drug in interstate commerce in "good faith" and had shipped it to a retailer. It was also conceded that the defendant had fully complied with the Act in that it had supplied FDA with the name and address of the person from whom it had purchased the drug, together with "copies of all documents . . . pertaining to the delivery" of the drug to it.[2]

In spite of this conceded compliance with the requirements of the guaranty provision, the District Court held that the defendant wholesaler was not entitled to guaranty protection and therefore could be prosecuted.

The legislative history, the decisions, and the policy of the Justice Department are all absolutely contrary to the conclusion reached by the District Court in *Moore*. But before discussing the right answer, we should point out the method chosen by the District Court in reaching the wrong answer.

Reasoning of the District Court

The Court began, in the usual way for food and drug decisions, by quoting from the *Dotterweich* decision, and others of similar vintage,[3] to the effect that because of the high purposes of the food and drug law special burdens are placed on those who deal in such products, and that it is against the background of these strict burdens that the scope of the guaranty clause must be examined. Having made this obeisance to the old truisms, the Court turned to the legislative history of the guaranty clause in the 1938 Act and the guaranty clause in the 1906 Act and noted, from a congressional committee report, that the guaranty clause "was intended to furnish protection to innocent receivers of goods forwarded to them in interstate commerce."[4] The Court concluded that the protection to be accorded "the innocent receiver" by the 1938 Act covered the same persons who had been

[2] Sec. 303(c) Federal Food, Drug and Cosmetic Act; 21 U. S. C. 333(c).

[3] *United States v. Dotterweich*, 320 U. S. 277, 282 (1943); *United States v. Balint*, 258 U. S. 250 (1922).

[4] S. 493, 73rd Cong., 2d Sess., p. 4.

protected by the 1906 Act. Thus, in order to discover who these "innocent receivers" are the Court quoted from Section 9 of the 1906 Act as follows:

> [*N*]*o dealer* shall be prosecuted under the provisions of this Act when he can establish a guaranty signed by the *wholesaler, jobber, manufacturer, or other party* residing in the United States, from whom he purchases such articles, to the effect that the same is not adulterated or misbranded within the meaning of this Act, designating it. Said guaranty, to afford protection, shall contain the name and address of the party or parties making the sale of such articles to such dealer, and in such case said party or parties shall be amenable to the prosecutions, fines, and other penalties which would attach, in due course, to the dealer under the provisions of this Act.[5] (Emphasis added.)

The Court examined the italicized portions of Section 9 and concluded that the dealer protected in line 1 must be someone other than the wholesaler, jobber, manufacturer, or other party mentioned. Since the defendant here was a wholesaler he could not have been the dealer mentioned in the first line of Section 9. Based upon this reasoning, the Court denied the motion.

Legislative History

The Court in *Moore* carried its research no further than this short examination of Section 9. Such a limited research was unfortunate for, if the Court had gone into the legislative history of Section 9, it would have discovered that Congress had been most explicit as to just who was to be protected by this section. In the House Committee report accompanying the bill which ultimately became the 1906 Act, the Committee stated that the guaranty section had been enacted in order "to protect all persons dealing in the articles subsequent to the manufacturer or importing agent."[6] The Committee then went on to compare the sample collecting provisions of the 1906 bill with the guaranty provision of that same Act and stated that ". . . if samples of goods shall be taken from a retail or wholesale dealer who has received a guaranty of conformity . . . he shall be relieved from prosecution."[7]

It is obvious that the legislative history of Section 9 of the 1906 Act directly contradicts the *Moore* reading of that section.

Position of the Justice Department

Furthermore, the position taken by the Court in *Moore* was not the position of the Justice Department in 1907. In 1907, the Attorney General, in an opinion to the Secretary of Agriculture, declared that the term "dealer" as used in Section 9, "includes those who deal in wholesale as well as those who deal in retail."[8] The Attorney General went

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[5] 34 Stat. 768, 771 (1906).

[6] H. R. 2118, 59th Cong., 1st Sess., p. 3.

[7] See footnote 6.

[8] 26 Ops. Atty. Gen. 450, 451 (1907).

on to say that the purpose of the guaranty provision was "to entirely relieve from prosecution any retail or wholesale dealer who had received a guaranty from the person from whom he purchased, and to prevent any dealer from being put to the expense of a prosecution to protect himself by requiring a guaranty."[9] There is no record that this position has ever been changed. Thus, the Justice Department, which presumably resisted the motion in the *Moore* case to dismiss charges, has itself for some 60 years held an opinion which would indicate that the Court in *Moore* misread the statute.

Decisional History

Finally, the decisional law also contradicts the *Moore* opinion. The Court did note that one case, *United States v. Levine,*[10] holds that wholesalers are protected if they have valid guaranties, and that *Levine* cannot otherwise be distinguished from the *Moore* case. The *Moore* Court respectfully declined to follow *Levine.* To do this, the *Moore* Court quoted from the Supreme Court decision in the *Wiesenfeld Warehouse* case[11] that the purpose of the Food, Drug and Cosmetic Act is to safeguard the consumer from the point of manufacture to the point of ultimate use, and that therefore the guaranty provision must be very narrowly construed. The *Levine* Court had, on the contrary, held that the guaranty section protected all innocent dealers, wherever they might be in the chain of distribution, if they complied with the guaranty Act.

Many of the other cases cited by the Court also contradict *Moore* in that the defendants in those cases were given the protection of the guaranty provision even though they were wholesalers or manufacturers. For instance, in the *Mayfield* case[12] the defendant was a manufacturer; in *American Stores*[13] the defendant presenting the motion was a wholesaler, and in *Dotterweich* itself the defendant was a manufacturer.[14] In none of these cases was it ever intimated that the guaranty provision did not apply to wholesalers or manufacturers.

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[9] 26 Ops. Atty. Gen. 450, 455 (1907).

[10] *United States v. Levine,* CCH FEDERAL FOOD, DRUG AND COSMETIC ACT, 1938-1949, Kleinfeld & Dunn, p. 367.

[11] *United States v. Wiesenfeld Warehouse Co.,* 376 U. S. 86 (1964).

[12] *United States v. Mayfield et al.,* 127 Fed. 765 (DC Ala., 1910).

[13] *United States v. American Stores et al.,* 183 F. Supp. 852 (DC Md., 1960).

[14] In *United States v. Balanced Foods,* 146 F. Supp. 154 (DC N. Y., 1955). The facts are not clear but the implication is that the defendants, who were found to have acted in "good faith" were wholesalers.

The *Moore* Court would have performed better had it observed the reasoning of the *Hall-Baker* case where the Eighth Circuit Court of Appeals noted that "the [1906] Act of Congress was not enacted to catch and punish merchants . . . for the mistakes of third persons over whom they have no control."[15] This was the obvious purpose of the guaranty provisions.

Conclusion

The Court in *Moore* failed in every area of legal research. It gave too literal an interpretation to the words of the statute; it completely ignored relevant legislative history; it failed to take note of the opinion of the Justice Department at the time the original bill was new law; and, finally, it apparently chose to ignore the fact that all the relevant decisions were explicitly or implicitly contradictory to the position it ultimately reached. Hopefully, this decision will, unnoticed, retreat. **[The End]**

FDA FOOD LABELING REGULATIONS ISSUED

The Food and Drug Administration has issued regulations establishing new labeling requirements for food products (regulations covering drug and cosmetic labels will be proposed at a future date). The requirements will become effective December 31, 1967, for new packages and new or reordered label designs, but will not apply to existing stock until July 1, 1968.

Provisions concerning the statement of net quantity of contents require that it be placed in the lower 30% of the principal display panel, using a specific scale of type sizes. In packages containing less than 4 pounds or 1 gallon, net contents must be given in ounces. Qualifying words ("jumbo" pound) may not be used. The principal display panel must also identify the product and indicate the form in which it is offered. The location of the "principal display area" is specified for packages of various dimensions. There are also specific provisions as to embossed label information on glass and plastic containers.

If a package has a statement concerning the number of servings, the statement must be accompanied by a declaration of the net quantity of each serving. The declaration must comply with any quantitative definition contained in a voluntary product standard issued by the Department of Commerce.

A panel of the label must show the relative quantity of various ingredients by listing them in order of decreasing predominance. A quantitative declaration of any particularly expensive ingredient must be given.

The regulations give details on the exemption from labeling requirements granted to transparent wrappers or containers, and spell out procedures for obtaining other exemptions, including those for small packages. Reg. Secs. 3.57, 1.1—1.10, CCH Food Drug Cosmetic Law Reports, ¶ 4057, 9851—9887.

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[15] *Hall-Baker Grain Co. v. United States*, 198 Fed. 614, 619 (CA-8, 1912).

Latin-American Food Code 1964 Edition

In August 1964, the Latin-American Food Code Council Published the Second Edition of the Latin-American Food Code. Information Concerning the Code and the Table of Contents of the New Edition Appeared in the April 1965 Issue of the *Food Drug Cosmetic Law Journal* (Vol. 20, page 238). The First Five Chapters Were Published in the September 1965 Issue; Chapters XII and XIII in the October 1965 Issue; Chapter XVII in the November 1965 Issue; Chapter X in the December 1965 Issue; Chapter VII in the June 1966 Issue; Chapter XVIII in the August 1966 Issue; and Chapter XVI in the May 1967 Issue. Chapter VI Appears Below. The Translation Is by Ann M. Wolf of New York City.

Chapter VI: Meats and Similar Foods

Fresh and Canned Meat

Article 87—The generic name "meat" means the clean, healthy, edible part of the muscle of cattle, sheep, hogs, goats and other animals which, before and after slaughter, have been declared suitable for human consumption by the meat inspection authorities. By extension, it also means the edible parts of fowl, game, fish, crustaceans and shellfish. The name "Beef" means the meat of cattle slaughtered in slaughterhouses.

Article 88—Butcher shops, markets and/or stands which sell meat, fowl, fish, crustaceans and shellfish shall comply with the general regulations and, in addition, meet such requirements as the local authorities may fix. Dogs, cats and other animals shall not be permitted in meat markets, butcher shops and slaughterhouses.

Article 89—The term "Fresh meat" means the aired meat of freshly slaughtered animals, whose principal characteristics have not undergone any essential change and whose color, odor and consistency are normal. Meat not sold within 24 hours after slaughter must be kept in cold-storage rooms or cellars at a temperature of between 4 and 5° C.

Article 90—The term "high meat" means meat which, due to incipient surface spoilage, has lost the characteristics of fresh meat.

Article 91—Meat is considered "thin," or "lean," when at first sight, no fat or fibrous tissue is visible; "medium," when it contains little fat; "fat," when it contains macroscopic fat in a regular or abundant amount, and "fibrous," when connective tissue predominates in it.

Article 92—The following organs are considered viscera, entrails, or guts: the heart, sweetbreads, liver, spleen, rumen, omasum, reticulum and abomasum of ruminants; the tripe, small intestine, rectum, diaphragm, kidneys, lungs, brain, spinal cord, and fore and hind feet of hogs and sheep.

Article 93—Fresh meat intended for human consumption must be shipped as follows:

1. In special closed railroad cars, trucks or carts, which are lined with zinc, are not used for any other purpose and are kept at all times in perfect sanitary condition and protected from contamination by dust, insects, etc. Wherever possible, preference shall be given to refrigerated vehicles.

2. In wicker, wood, or waterproof canvas containers, which shall be kept perfectly clean and in good condition. When fresh meat intended for human consumption is shipped pre-cut into portions, such portions must first be wrapped in waterproof paper.

Article 94—The following meats are prohibited from being sold or used in preparations intended for human consumption: meat from diseased animals; high meat, or meat which on litmus paper has an alkaline, amphoteric or neutral reaction; meat which blackens a paper impregnated with lead subacetate or shows traces of spoilage; meat containing volatile basic nitrogen in a proportion of more than 125 milligrams per hundred grams of dry residue; meat contaminated by micro-organisms, insects or larvae, dirt or dust; meat coming from fetuses, unborn or still-born animals, meat that has a bad odor, and meat treated with prohibited colors or preservatives.

Any such meat found on the market shall be seized summarily and the persons trading in it shall be penalized.

Meat intended for human consumption is prohibited from being packed or wrapped in printed paper or second-hand burlap.

For reasons of hygiene (contamination), meat tenderizing devices which perforate the meat or make deep parallel cuts that separate

muscles, aponeuroses and tendons are prohibited from being manufactured, sold or used.

Article 95—The term "Chopped" or "ground" meat means meat finely ground by mechanical processes, suitable for human consumption.

Ground meat shall be prepared in the presence and at the request of the purchaser, and the holding and sale of pre-ground meat are prohibited; if found, it will be seized summarily.

Article 96—The term "Chilled beef" means beef from good breeds of properly fattened cattle, chilled to a temperature of about –2° C.

Article 97—The generic name "Frozen Meat" means meat hard frozen to a temperature of between –10° and –20° C. in a cold-storage chamber or cellar. Such meat can come from cattle (frozen beef, or hard beef), sheep (frozen mutton) or hogs (frozen pork).

Article 98—The term "Baby Beef" means meat from cattle (calves, young bulls, or steers) since birth fattened rapidly by means of a special heavy diet in order to have it reach a specific size by the age of 12 to 14 months and to obtain a high-grade thick meat in the shortest possible time.

Article 99—Poultry may be sold live or killed.

Live poultry shall be subject to inspection and be kept in suitable places and satisfactory hygienic conditions to ensure its perfect state until it is sold to the public.

Killed poultry may be sold whole (with or without the feathers), or eviscerated, in which latter case the giblets, properly wrapped, may be placed in the abdominal cavity. Poultry shall be killed on premises which, like slaughterhouses and stripping houses, have been approved by the health authority, which shall control slaughtering operations continuously.

Killed poultry, eviscerated or not, may be treated by immersion in antibiotics in accordance with Article 43 of this Code, provided that the consumer be advised of such treatment on a band, tag, label, etc.

Article 100—The term "Broiler" means a young chicken of either sex, not more than three months old, whose flesh is very tender and whose bones are still soft. Broilers are usually grown at special hatcheries on specific feeds.

Article 101—The term "fresh fish" means fish which has not undergone any preservation process and is in good condition. Fish must be stored in refrigerators or ice-filled vessels at fisheries, fish outlets and while in transit.

At fresh fish outlets, the following table must be posted prominently for the information of consumers:

	Fresh Fish	Spoiled Fish
Gills	Strong red color	Reddish brown color
Belly	Pink, not protruding	Dark and protruding
Meat	Firm and resilient	Flabby
Scales	Bright	Dull and loose
Eyes	Bright, not sunk in	Dull and sunk in
Body	Perfect	Often broken
Muscular tissue	White	Pink

Article 102—Fish and crustaceans sold for immediate consumption or canning must not only look perfect, but in addition, must not have a positive indole reaction, may not contain volatile basic nitrogen in a proportion of more than 125 milligrams per 100 grams of dry residue or have a pH of more than 7.5.

Article 103—All fish intended for immediate consumption or canning must be packed in adequate vessels immediately after landing. Salt water fish may not be washed in fresh water, and vice versa, before being put on the market.

Article 104—Fish markets and stands at which fish and other seafood are sold shall be operated on special premises, which may be connected with other stores. In addition to meeting the general standards, they shall comply with the following requirements:

They shall have flat ceilings, waterproof floors with a rounded cove base, and wainscots at least 1.80 meters high made of tiles, white cement or another authorized material. They shall have marble and wood tables; tiled basins in which to keep fish and other seafood under ice, and refrigerators.

Article 105—All fish must be sold under its precise name, and the food laws of each country shall state both the name used in the local idiom and the scientific name of each fish.

Article 106—Raw fish is prohibited from being sold pre-cut into fillets or parts; the purchaser must be shown the whole fish,

complete with head, eyes and gills. It may be filleted or cut into parts only at the request and in front of the purchaser who takes it with him immediately. By way of exception, raw fish may be sold in fillets or parts when, under a special permit to be issued from case to case by the health authority, the fish is kept chilled from the time of landing to its arrival at the plant, the fillets and/or parts are kept frozen or chilled to the time of their sale to the public and the establishment is inspected regularly by the health authority. All containers from which such fish is sold to the public must bear the date on which the fish was sectioned.

Any fish, part or fillet with a pH exceeding 7.5 and containing ammonia nitrogen in an amount of more than 125 mgs. per 100 grams of dry residue shall be destroyed summarily.

Article 107—The keeping or sale of shrimps and prawns not killed immediately after landing by immersion in boiling water (with or without the addition of vinegar) is prohibited. Shrimps and prawns must be chilled before being packed for shipping.

Shrimps and prawns shall have the following characteristics: a red shell, firm consistency, a strong but pleasant odor, the tail bent under the thorax, firm white meat.

By way of exception, a very slight ammonia reaction shall be tolerated.

Article 108—Other crustaceans (crabs, lobsters) shall be sold live; they shall respond to the slightest excitation and have a moist, glistening shell.

Article 109—Bivalve shellfish (oysters, scallops, mussels) shall be sold live and have the following characteristics: they must be heavy, the valves must be closed; when touching each other they must produce a dull sound; they must contain an abundant amount of water, and the shell must respond to excitation. Any bivalve shellfish found with its valves open shall be seized on the spot.

Cephaloped shellfish (squids, octopuses, cuttlefish) must have a moist soft skin, bright eyes and elastic firm meat.

Gastroped shellfish (snails) shall be sold live, shall fill their shell completely, be firmly attached to it and have mobility.

As an exception to Article 17, the presence of lead in shellfish and crustaceans shall be considered normal in a proportion of up to 2.8

p.p.m. in the fresh edible part, and in a proportion of up to 20 p.p.m. in the shell of fresh crustaceans; the presence of arsenic in the fresh edible part shall be considered normal in a proportion of up to 30 p.p.m.

Article 110—Seafood shall be considered unsuitable for human consumption and be seized summarily:

1. If it is in a state of spoilage or violates Articles 101, 102 and 103;
2. If its contains unauthorized preservatives (except common salt);
3. If it was caught under poor conditions or from contaminated waters;
4. If it was caught floating, dead, or dying, overturned, injured, mutilated, or maimed;
5. If it shows signs of microbial, parasitic or toxic disease;
6. If it is marketed in poor sanitary conditions, in dirty baskets or vessels, close to burlap bags or next to fruits or vegetables;
7. If it is sold mutilated;
8. If, for some other reason, it is unfit for human consumption or canning (unpleasant flavor or appearance, etc.).

Article 111—Fresh game obtained from mammals or fowl may be sold only during the open season, always provided that its sale is not in conflict with specific local hunting laws and regulations.

Game packing houses and canneries are permitted to purchase the animals only during the hunting season, whereas canned game may be sold at any time after it has been inspected, the canning date has been checked and it has been released for sale.

The sale and canning of game killed by sports hunters is strictly prohibited at any time.

Products from game animals raised in captivity the consumption of which has been authorized, and canned game the canning of which was permitted, may be sold at any time after registration of the breeder, issuance of a certificate of origin and identification of the live animals, or cuts.

The sanitary conditions under which game may be sold to the public shall be fixed in each case by the competent authority.

Any, natural or processed, game from animals bred in captivity sold in violation of this article shall be seized summarily.

Article 112—Any products prepared from game animals, wild or bred in captivity, the sale of which has been authorized for human consumption in fresh or processed (canned) form, must be sold under its common or vernacular name, or, as the only alternative, under its generic scientific name.

Article 113—The term "meat-packing plant" means any establishment which slaughters animals, processes meats and meat by-products and has refrigeration and cold-storage facilities. Packing plants shall comply with all the requirements established in this Code for the various operations they perform, and, in addition, shall meet the general standards and additional provisions of the jurisdictions within which they operate.

Article 114—The following products may be added to preserved foods of animal origin and similar products without first obtaining a permit; milk, eggs, aromatics, onions, parsley, garlic, sodium chloride, sugars, honey, and starchy substances (flours, feculae and starches) in a proportion of not more than 5 percent. When the starch content exceeds 5 percent, it must be declared on the principal label, except on liver, fish and shellfish pastes (Article 116, point 37, and Article 149). The so-called "curing liquids" may contain the following ingredients: saltpeter (sodium or potassium nitrate) in such an amount that the nitrate residue in the cured product does not exceed 0.30 percent; sodium nitrite, always provided that the residue in the cured product does not exceed 0.02 percent; disodium phosphate, sodium hexametaphosphate, trisodium polyphosphate, sodium pyrophosphate, sodium acid pyrophosphate, and polyphosphates of sodium and potassium suitable for use in foods in a concentration not exceeding 5 percent, with the proviso that the cured product may not contain phosphate in a proportion of more than 0.5 percent. The use of phosphates shall not cause a significant increase in the normal water content of the finished product.

The use of horse, dog or cat meat or fat in the preparation of preserved meats, sausages and similar products is prohibited.

Article 115—Canned foods in general shall be considered adulterated if they contain water, brine, syrup, gravy or similar substances in amounts exceeding the quantity required to ensure the preservation or sterilization of the product.

Article 116—The following generic names designate the products defined hereinafter:

1. *Roast Beef:* Beef roasted on the spit, in the broiler, on the grill or in the oven. Average percentage composition: water 60; protein 26; fat 3; ash 1.

2. *Steak and Onions:* The canned product made from slices of beef and a gravy with an onion base. The name "Grilled sirloin steak" designates the canned steak prepared from grilled beef loin.

3. *Bondiola:** Meat from the neck of hogs, stripped of its fat and skin, cured in brine, and wrapped in the large intestine of cattle, tied securely and properly dried.

4. *Buseca:** A soup prepared from strips of tender calf tripe, bacon and seasoning.

5. *Ready-to-serve Broths:* The name "Meat Broth" designates the solid, semi-solid or liquid product consisting of a mixture of extracts of fat or fatless meat, salt, condiments, monosodium glutamate, and/or other authorized substances. Solid concentrated broths may not contain water in a proportion of more than 8 percent, fatty matter in a proportion of more than 25 percent and sodium chloride in a proportion of more than 60 percent; its amino-nitrogen content must not be less than 1.3 percent and its creatinine content not less than 0.4 percent. Liquid concentrated broths shall contain dry matter in a proportion of not less than 30 percent. Products designated by the name of a specific meat (chicken broth, etc.) must contain the meat named in a proportion sufficient to give the product the corresponding organoleptic characteristics.

6. *Smoked Meat:* Meat which has been subjected to the direct action of smoke coming from the combustion of firewood, with or without the addition of aromatics. See Article 119.

7. *Corned Beef:* Boned beef, cured and cooked. Instead of beef, meat from sheep or hogs may be used (Corned Mutton, or Corned Pork).

Average percentage composition (Corned Beef): Water 52; protein 26; fat 18; ash 4.

8. *Corned Beef Hash:* A preparation made from finely cut preserved meat, boiled potatoes and seasonings.

9. *Cured Meat:* Meat which has undergone a curing process using common salt or brine, with or without the addition of the following products: sodium nitrite, sodium or potassium nitrate, honey, spices, wine, beer, and various sugars.

10. *Seasoned Beef* (Boeuf assaisonné): Boned beef, which may have been left in brine for some time, to which several vegetable seasonings have been added.

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* Note of the Translator: A product peculiar to Latin America which has no equivalent in the United States.

11. *Dried Beef* ("Charque"): Lean beef, prepared in thin slices, cured and dried under sanitary conditions in the open air or in special ovens. "Charque" prepared from the meat of other animal species shall bear the name of the species.

Percentage composition: water 17 to 35; protein 59 to 72; fat 3 to 6; ash 3 to 5 (sodium chloride 2 to 3).

Jerked Beef ("Tasajo") is beef preserved by drying and salting. Mild or sweet "Tasajo" contains salt in a proportion of less than 10 percent.

Percentage composition: water 21 to 38; protein 36 to 54; fat 0.3 to 8; glucides 0.4 to 0.8; ash 12 to 17 (sodium chloride 10 to 16).

Whole chunks of jerked beef ("tasajo") and dried beef ("charque") taken from the rib area are usually named "mantas," those taken from other parts "postas." The name "chalona" designates the dried salted meat of sheep. Both jerked or dried beef and "chalona" may not be rancid, swollen, greasy, infested with worms or spotted and shall meet the requirements fixed in Article 94.

12. *Boiled Beef:* Boneless beef, cooked and salted. Instead of beef, mutton may be used (Boiled Mutton).

Average percentage composition (Boiled Beef): water 55; protein 25; fat 19; ash 1.

13. *Ox Tails:* The first coccygeal vertebrae of cattle, cured in brine, seasoned and cooked.

Average percentage composition: water 65; protein 26; fat 8; ash 1.

14. *Irish Stew:* A stew prepared with lamb, potatoes and white sauce.

15. *Cassoulet:* A stew prepared with white beans, meat, chunks of sausage and a suitable sauce.

16. *Sausage Stuffing:* Pickled pork, or a mixture of ground meat, bacon and seasoning intended for the preparation of sausage.

17. *Chili con carne:* A stew prepared from small pieces of beef or pork and beans, hot chili sauce and other seasonings.

18. *Appetizers:* This term designates the lips of cattle or hogs cut into small pieces and cured in brine, cooked and packed with vinegar and spices.

19. *Stewed Beef:* Chunks of beef seasoned with gravy or "tuco."*

20. *Meat Broth Extract or Meat Extract:* A broth prepared from fatless meat, tendons, cartilages and bones, filtered and concentrated

* Note of the Translator:
"Tuco" is a type of spaghetti sauce used in Latin America.

to liquid or pasty consistency (liquid or solid extract). It may not be named "Double concentrate." It may contain only traces of substances soluble in cold water; it must contain not less than 60 percent of substances soluble in 80° G. L. alcohol; not more than 22 percent of water, 1.5 percent of fatty matter, 10 percent of sodium chloride and 0.50 percent of ammonia nitrogen; not less than 7 percent of total nitrogen and 5 percent of creatinine. It may contain traces of glue and gelatine, but must be free from dextrines, coagulable albumins, caseine derivatives, yeast extracts and other foreign matter.

21. *Boneless Pigs' Feet in Jelly:* A preparation with a base of boneless pigs' feet, cured in brine and then boiled in water, which is packed with a small amount of gelatine or agar-agar.

22. *Lamb Stew:* A stew prepared with lamb and gravy.

23. *Kidney Stew:* A stew prepared with chunks of beef, beef kidneys and gravy.

24. *Foie Gras:* The livers of geese or ducks fattened by a special diet. The term "Pâté de Foie Gras" and other names including the words "foie gras" mean pastes containing fattened goose or duck liver in a proportion of not less than 20 percent. They may not contain water in a proportion of more than 75% calculated on the fat-free product.

25. *Deviled Ham:* A paste made of cooked pork in a proportion of not less than 51 percent, seasoned with pepper and other spices.

Average percentage composition: water 45; protein 19; fat 33; ash 3.

26. *Cured Ham:* The thigh of the hog cured in brine and properly aged while protected from infestation. Depending upon the process used in its preparation, ham is classified into: English (York); German (Hamburg, Westphalian); French (boneless, Bayonne type); Sierra (lean and smoked) etc. cured ham. Average percentage composition: (Cured fat ham): water 45; protein 12; fat 42; ash 0.5; (Cured semi-fat ham): water 54; protein 16; fat 29; ash 0.8. (Cured lean ham): water 60; protein 17; fat 22; ash 0.8.

27. *Boiled Ham:* Ham boiled in water after curing, with or without the bone, with or without condiments. Depending upon the process used for its preparation it is classified into: Tenderized or smoked boiled ham, in the preparation of which no proteolytic enzymes, such as papain, may be used; French ham (Paris or Reims type); German ham (Berlin type), etc.

Average percentage composition: water 55; protein 18; fat 20; ash 0.6.

28. *Beef Extract:* The liquid part of the muscular tissue, unconcentrated, or concentrated at a temperature below the coagulation point of the soluble protein, or under vacuum. It may not contain any foreign matter; the dry residue shall not yield ash in a proportion of more than 15 percent, and the ash may not contain sodium chloride in a proportion of more than 2.5 percent; the amount of phosphoric anhydride shall fluctuate between 2 and 4 percent, and the amount of nitrogen shall not be less than 12 percent, both calculated on the dry residue; the nitrogenous portion shall not contain more than 35 percent of coagulable albumin or more than 40 percent of creatine bases.

29. *Sheep or Lamb Tongue:* The tongues of sheep or lamb from which the surface membranes (mucosa) have been removed, free from bones and laryngeal and tracheal cartilage, cured for a certain time in brine and then cooked. Gelatinous broth may be added to them in canning.

Ox tongues, veal tongues and pork tongues are prepared in the same manner. The animal species from which they come must be named in the labeling.

Average percentage composition: Sheep tongue: water 50; protein 20; fat 26; ash 4. Beef tongue: water 55; protein 19; fat 22; ash 4.

Tongues may also be packed with pickling sauce in which case they shall be named: Pickled Sheep Tongue, Pickled Lamb Tongue, Pickled Pork Tongue, Pickled Luncheon Tongue.

30. *Braised Lamb Tongue in Savoury Sauce:* This type of tongue is prepared as described at point 29, except that seasoned tomato sauce is added to it during canning.

31. *"Locro" or "Locro Criollo":* A stew prepared with crushed corn, beans, meat chunks, squash and seasonings. If wheat is used instead of corn, the stew is called "Locro de trigo."

32. *Canadian Bacon:* Loin of pork, cured and smoked.

33. *Minestrone:* A soup prepared with vegetables, dried vegetables and seasonings, with or without rice or noodles.

34. *Shredded dried Tripe:* Clean beef rennet, washed in hot water, cut into strips or small chunks, and dried. Cooked tripe is the same, cooked in salt water, de-fatted and seasoned.

35. *Meat Paste, Mince Meat:* A paste prepared with veal, young beef, etc., bacon and seasonings.

36. *Potted Ham, Potted Chicken, Potted Turkey* and similar products: Seasoned pastes containing ham, chicken or turkey in a proportion of not less than 51 percent.

37. *Liver Paste, Pâté de foie:* A preparation made with pork liver in a proportion of not less than 25 percent, pork fat, beef and pork sausage, milk, eggs, seasonings, and starch in a proportion of not more than 10 percent. Its moisture content may not exceed 65 percent calculated on the fat-free product. Liver pastes with mushrooms must contain dried mushrooms in a proportion of not less than 6 grams per kilo.

38. *Potted Tongue or Tongue Paste:* A paste made with tongue, prepared as provided for at point 29, in a proportion of not less than 15 percent, and various seasonings.

39. *Brisket of Beef:* Meat from the brisket of cattle, cured, seasoned and cooked.

Average percentage composition: water 51; protein 18; fat 25; ash 6.

40. *Ox Cheek:* Cured and cooked ox cheeks.

41. *Ragout:* A stew prepared with chunks of meat, vegetables and various seasonings.

42. *Ravioli or noodles in "tuco"* (spaghetti sauce): Ravioli or noodles, cooked and dressed with gravy or spaghetti sauce.

43. *Concentrated Soups:* Mixtures of meat extracts and fats, seasonings, cereal or vegetable flours, dehydrated vegetables, vegetable extracts, powdered milk derivatives and other authorized products. Such soups may not contain water in a proportion of more than 16 percent or ash in a proportion of more than 20 percent. Soups named: "Cream of....." shall, after dilution in the volume of water prescribed on the label or tag (for instance, 4 times its amount or a liter of water) not contain fat in a proportion of more than 2.5 percent.

Article 117—Salted meats and bones kept in storage and/or displayed for sale shall be kept in impervious containers.

Article 118—Dried meats, regardless of whether or not they were salted and/or smoked, shall not be flabby or brittle, shall not smell of trimethylamine, shall not have an alkaline reaction, red or other spots, and shall not contain more than 125 milligrams of ammonia nitrogen or 50 grams of hydrogen sulphide per 100 grams of dry product.

Article 119—The smoking shall preferably be performed with "smoke oil" (Article 659) with a low 3.4 benzpyrene content and may be followed by ordinary smoking of short duration.

Eggs

Article 120—Under the general term "Eggs" only fresh hens' eggs which have undergone no treatment other than mechanical cleansing may be sold.

Eggs of other birds shall be sold under the name of the bird that laid them: duck, ostrich, goose, turkey eggs, etc.

The term "Fresh eggs" may be used only for eggs which, when candled in the ovoscope, look perfectly clear, without shadows of any sort, with a hardly visible yolk and a small air cell not more than 10 millimeters deep. The shell must be strong, uncracked and clean without washing; the white must be firm, clear, free from spots, and very homogeneous, and the yolk must be uniform in color, from light yellow to reddish, well centered, and firm, and must remain whole and flatten lightly when the egg is broken on a plate. The average quantity of ammonia nitrogen contained in both white and yolk shall fluctuate between 2.2 and 3 milligrams percent; the pH of the white shall be 7.6 and that of the yolk 6.4. Moreover, when observed under filtered ultraviolet rays (Wood's light) a fresh egg shall give a reddish, never a bluish color, and the white must not fluoresce, but have a transparent blue color.

Average percentage composition: Fresh chicken eggs (edible part): water 74; protein 12; fat 11; glucides 2; ash 1. Fresh duck eggs: water 71; protein 13; fat 14; glucides 1; ash 1. Fresh goose eggs: water 70; protein 14; fat 13; glucides 2; ash 1. Fresh turkey eggs: water 72; protein 13; fat 12; glucides 2; ash 1.

Fresh eggs may be sold as such even after they have been kept in cold storage for up to eight days, always provided that they meet the requirements fixed in this article. A fresh egg shall be labeled "chilled" if it was kept in artificial cold for up to 30 days; "refrigerated" if it has been in cold storage for more than 30 days; an egg preserved in a special gaseous medium (nitrogen, carbon dioxide, etc.) shall be labeled "stabilized" and an egg subjected to temperatures of between –12° and –18° C. (slow freezing) or –25° C. (quick freezing) shall be labeled "frozen."

Article 121—Eggs preserved by insulation with inert matter (sawdust, bran, straw, etc.), by processing with petroleum jelly, paraffin, wax, gum resin, collodion, etc., by immersion in solutions of lime water, water-glass, or by another process authorized by the authorities shall be sold with a clearly visible label bearing the legend "Preserved" in letters not less than 2 millimeters high and the registration number and/or initials of the seller. More-

over, any containers, cases, boxes, etc. used for eggs thus processed shall be labeled "Preserved eggs" at a visible spot and in clearly legible letters together with whatever additional markings are required. The eggs selected for preservation shall preferably be so-called "plasma-less," sterile eggs.

Article 122—Eggs shall be considered unfit for human consumption, but suitable for industrial uses (in industries other than the food industry) if they show dark spots when candled; if after the shell is broken the yolk separates easily and the white has lost its consistency and is two or three times as large as the white in a fresh egg; if under filtered ultraviolet light, the yolk produces a blue, green, purple or reddish milky fluorescence; if the average ammonia nitrogen content of the white and the yolk exceeds 3.1 milligrams per 100 grams and their average pH exceeds 9.

Article 123—The grading of eggs may not be performed on premises where foods or beverages are prepared or where eggs are sold to the public. The existence on such sites of ungraded or inedible eggs shall be considered as a punishable offence even if it cannot be proved that they were intended for use or sale.

Addled eggs, eggs infected with bacteria or fungi, rotten eggs, bad-tasting eggs, eggs with green whites, eggs showing blood rings, eggs containing embryo chicks, eggs having spots of a microbic origin or a cracked shell, eggs of birds not properly fed, eggs processed by unauthorized processes or otherwise contaminated shall be considered unsuitable for any use whatsoever and for this reason shall be summarily destroyed.

Batches of eggs intended for human consumption in which the proportion of inedible eggs reaches or exceeds 25 percent shall be summarily destroyed, and the same shall be done with batches of eggs from cold-storage rooms or preservation tanks in which the percentage of inedible eggs exceeds 15 percent.

Eggs intended for purposes other than food shall be denatured by the addition of strong-smelling substances, camphorated oil, turpentine spirits or other substances specifically approved by the competent authority.

Article 124—The term "frozen liquid egg" means the meat of hens' eggs removed from the shell, packaged in containers of glass or another suitable material sealed hermetically and stored in a cold-storage room (Article 120). When the

egg comes from another bird, this shall be stated in the labeling used on the container. Before handling, the eggs shall be graded, and spoiled eggs shall be discarded and destroyed. Moreover, the eggs shall be washed before breaking to remove any impurities adhering to them, and then rinsed with potable water. In this industry, only sound eggs which have no trace of spoilage and whose shells are in perfect condition without any cracks may be used.

Article 125—The terms "powdered egg" and "dried egg" mean the product obtained by evaporating the water in the white and the yolk of the egg. Dried egg shall meet the following specifications:

Grade A: Homogeneous appearance: velvety texture; uniform yellow color; odor "sui generis"; pleasant flavor; moisture, not more than 5 percent; ether extract, not less than 38.5 percent; acidity of the ether extract, not more than 2 milliliters of 0.05 N sodium ethylate per gram; total protein, not less than 40 percent; amount of nonpathogenic germs, not more than 500,000 per gram; free from bacteria usually considered pathogenic for man; free from coloring matters, preservatives and adulterants.

Grade B: Homogeneous appearance: texture granulated, but not rough; color, pale yellow or greyish-yellow; odor, slightly acid, but not sour; flavor, slightly different from that of fresh eggs, but not unpleasant; moisture, not more than 6 percent; ether extract, not less than 37 percent; acidity of ether extract, not more than 3 milliliters of 0.05 N sodium ethylate per gram; total protein, not less than 40 percent; amount of nonpathogenic bacteria, not more than 800,000 per gram; free from pathogenic bacteria; free from coloring matters, preservatives and adulterants.

Average percentage composition (Dried whole eggs): water 4.5; protein 1; fat 41; glucide 3.5; ash 4.

Sugars may be added provided that the sugar content is declared in the labeling.

Article 126—The term "Egg yolk" means the product obtained by removing the white, of which not more than 12 percent may be present in "egg yolk." Average percentage composition (Hen's egg): water 50; protein 16; fat 32; glucide 0.8; ash 1.2.

Powdered or dried egg yolk is the same product after removal of its water content. It shall meet the following specifications: moisture, not more than 5 percent; ether extract, not less than 40 percent;

acidity of the ether extract, not more than 3 milliliters of 0.05 N sodium ethylate per gram; total protein, not less than 32 percent; ash, not more than 4 percent; bacteria, 500,000 per gram.

The term "egg white" means the product obtained by the elimination of the yolk. Average percentage composition (Hen's egg): water 88; protein 10.8; fat 0.2; glucides 0.6; ash 0.4. Dried Egg White is the same product after removal of its water content. It may not contain moisture in a proportion of more than 13 percent.

Slaughterhouses

Article 127—The term "Slaughterhouse" means any establishment at which beasts intended for human consumption are butchered.

Whenever possible slaughterhouses shall be located on sites removed from urban conglomerations, at locations distant from establishments which give off odors, smoke or dust, such as: mineral mills, lime factories, oil refineries, chemical plants, etc., and in regions where floods do not occur. Their hallways, from the plant entrance to the processing room, shall be waterproof and properly lighted and all adjacent spaces shall be covered with turf or waterproofed. They shall be surrounded by a wire fence, 2 m. high, topped by barbed wire to keep men and animals out.

a. Cattle intended for food may not be slaughtered, dissected, skinned or stripped outside the slaughterhouse, and animals may not be butchered unless they have been inspected by the Official Meat Inspector (Veterinary Officer) and released for killing. No public slaughterhouses of any type may be installed and operated without a license from the health authority.

b. The meat, entrails and other parts of animals killed for human consumption may not leave the slaughterhouse, nor may they be processed or stored without an examination by and an authorization from the Official Meat Inspector.

c. Slaughterhouses shall be provided with every facility required to permit meat inspectors to examine the animals and perform their inspections in comfort. Overtime work is prohibited without the knowledge of and an authorization from the meat inspection authorities.

d. Dogs are prohibited inside slaughterhouses. The entrails of diseased animals are prohibited from being kept and shall be destroyed. For infractions of these rules the men in charge or managers of the slaughterhouses shall be personally liable, jointly with the organization, company, or individual that owns the business.

e. At no time may meat be dressed on the floor, an operation to be performed only at butcher shops or meat markets on suitable tables, or while the carcass is hanging.

f. In towns and villages which have no public slaughterhouses, slaughtering may take place on sites approved for this purpose by the municipal health authorities. The sites must be elevated, and at least 500 meters away from the town limits.

g. No slaughterhouse may ever be used for purposes other than slaughtering.

h. All animals intended for slaughter shall remain in shaded holding pens for not less than six to twelve hours, during which time the following requirements must be met:

1. Any animal suspected of a disease shall be placed in a separate pen, where it shall remain for 24 hours. If it is found to suffer from a contagious or infectious disease, it shall be killed and destroyed, and the health authority shall be notified thereof. If the symptoms have disappeared after 24 hours, it may after inspection by the Official Inspector be sent to the killing floor. If an animal is afflicted with a noncontagious disease, it may be returned to the owner and be slaughtered after the time required for complete recovery.

2. Any animal found in the holding pen of a slaughterhouse dead, dying or with a fractured limb may be seized if so ordered by the health authority after a post-mortem examination.

3. Any animals which escape and/or get excited on the way to the killing floor shall rest for an hour before slaughter.

4. Animals which were run or are footsore may be slaughtered only after a rest of at least 6 hours in the holding pen of the slaughterhouse.

5. To prevent suffering, an injured animal may be killed even if no Official Health Inspector is present, but the carcass must be left whole for inspection, with the head and all viscera, except stomach, bladder and intestines, in their natural position. Otherwise, it shall be seized, as shall happen also if it can be proved that the animal was injured or diseased.

6. All slaughtered animals must be shown to the Official Health Inspector whole, or cut into halves, with their splanchnic serous membranes intact, and with ganglions, lungs, heart, liver, spleen and head attached to the body by their natural anatomic ligaments.

7. Fetuses shall be seized, but may be used for research work under special control.

Article 128—Animals afflicted with any one of the following diseases shall be seized whole: General actinobacillosis; general actinomycosis; caseous adenitis with extended lesions; cachexia; symptomatic carbuncle following a pathological condition; general cysticercosis; cholera; Texas fever (Pyroplasmosis and Anaplasmosis); jaundice after an infection or poisoning which imparts a yellow color to the fat, flesh, aponeurosis or bones; general parasitic infection; general melanosis; pyoemia; sarcoporidiosis; gangrenous septicemia; hemorrhagic septicemia; trichinosis; melancholia and other pathological conditions provided for in the national Food Laws of a country.

Article 129—Seizures may be partial if lesions can be proved to be small and localized in cases of: actinobacillosis; actinomycosis; caseous adenitis; cysticercosis; cholera; dysthomatosis; equinococosis; tuberculosis and other diseases provided for in the national Food Laws of a country.

Article 130—Meats found suitable for human consumption shall be stamped or strapped by the Official Meat Inspectors. For purposes of control, retailers shall sell last the parts bearing the stamps or straps. In case of failure to comply with this requirement, no explanation can prevent the imposition of the established penalty.

Any carcass, or carcass part, which, after final inspection, is found defective, unsanitary, unwholesome or otherwise in a condition that makes it unsuitable for human consumption must be marked with a stamp "Not for consumption" and cut across several times.

Any parts of the carcass or organs to which, due to their nature, such stamp cannot be affixed, shall be separated and stored in special vessels. Rejected carcasses, carcass parts and organs shall remain under the control of the Official Meat Inspection Department until taken to digesters for destruction. If not destroyed the same day, they shall be kept in compartments intended only for this purpose. Any carcasses not bearing the regulatory stamp or strap shall be considered as coming from clandestine slaughterhouses and shall be seized summarily, and offenders shall be penalized in accordance with the law.

The concealment of uninspected carcasses or parts shall be punished with seizure and the established penalty. The removal of ganglions,

pleura, peritoneum, or parietals, or of part or all of the organs, or severance of the same, shall be liable to complete seizure and the imposition of the established penalty.

Any treatment or process applied to improve the appearance of meat, or to mislead the purchaser about its actual condition shall be punished with the established penalty. If such treatment or process also renders the meat harmful, criminal proceedings may be instituted.

If owners or operators make false statements about the number of animals ready for slaughter or already slaughtered at their establishments, their license will be temporarily suspended by the health authority, without prejudice to the imposition of the established penalty.

In localities which have no permanent health inspection services, retailers shall keep ganglions and entrails, except the gastrointestinal tract, available for periodic inspections until the meat is sold, after which time they may sell the entrails.

Article 131—Seized meats and meat products shall be destroyed in digesters, under the supervision of an official health inspector, at a temperature of not less than 105° C. and for four hours, or else in special ovens or boilers.

At plants which have no digesters in which to destroy seized products, these products shall be denatured with creolin or another agent approved by the competent authority, or be incinerated. Such operations shall always be performed in the presence of an official health inspector.

Article 132—Official inspections of poultry shall be performed at collection centers both ante-mortem and post-mortem. Any poultry showing signs of one of the following diseases shall be seized: cachexia, cholera, diphtheria, cutaneous lymphoma, pip, tuberculosis, or any other disease that causes congestive alterations or, in the opinion of the inspector, justifies seizure. Seizure shall also take place when post-mortem alterations in the abdominal cavity (foul smell) or changes in the digestive organs and peritoneal tissue can be proved in dead animals or when their flesh shows alterations symptomatic of putrefaction.

Sausage Meat, Sausages and Similar Products

Article 133—The term "jerked beef" ("cecina") (See Article 116, point 11) means air-dried, sun-dried or smoke-dried salted or unsalted beef.

The term "spiced sausage pork" ("chacina") means not only cured pork and hog parts subjected to a preservation process (drying, salt-

ing, boiling, smoking), with or without casings (hams, salt pork, "bondiolas"), but also comminuted pork, with or without the addition of meats from other food animals, entrails and blood, to which may have been added bacon and various spices, sugars, ground cereals, starch (in a proportion of not more than 5 percent in the fresh and 10 percent in the cooked product), milk products, live lactic enzymes (Streptococcus lactis and Lactobacillus, both free from indologenous bacteria) in lactose or powdered milk, fresh or cooked products, eggs, fruits, vegetables and other permitted substances, ready for stuffing or filling. When such mixtures are encased in pieces of the small or the large intestine, or in other natural (bladder, esophagus, peritoneum, etc.) or synthetic casings, they become sausages, which may be fresh (frankfurters, "butiferra,"* pork sausage, blood pudding), preserved (pork sausage, salami, etc.) or cooked (bologna, "matambre," etc.) Sausages and other meat preparations are also called "Facturas" or "Hechuras." Cooked meats and sausages to be consumed cold are called "cold cuts."

Article 134—Sausages are classified into two groups:

a. Sausages made from pork and pork fat, with or without beef: FANCY GRADE.

b. Sausages made only from beef with pork fat: COMMON GRADE.

Pork fat or bacon is prohibited from being replaced by beef fat. In the labeling of both types, the proportion of meat of each animal species used in the preparation of the sausage shall be stated.

Article 135—The term "Delicatessen" ("Fiambrería," "Rôtisserie," or "Salsamentaría") means a store, or part of a store, in which sausages, cold cuts and hot meats, wines, various canned goods, etc. are sold.

Such shops shall have tables of marble or another suitable material, mechanical slicers, and refrigerators, and shall meet all other general standards.

Article 136—Sausage meat and other meat preparations shall be pleasant in odor and appearance and shall in addition meet the requirements fixed in Article 94.

They may not contain any sulphurous acid derivatives, saltpetre (potassium or sodium nitrate) in a proportion of more than 0.25 percent, or sodium nitrite in a proportion of more than 200 p. p. m. Ben-

* Note of the Translator:
A type of sausage first made in Catalonia.

zoic acid and benzoic acid salts may be added to sausages in a proportion of 1 per mil, if declared in the labeling.

Meats and entrails not inspected by an official health inspector are prohibited from being used. Raw materials and finished products from uninspected animals shall be seized summarily.

Article 137—Sausage meats from burst casings may be used in other products, always provided that such use takes place the same day they were prepared. They may never be kept from one day to the next if they are to be used in fresh products. If they cannot be used the same day, they may be used to prepare blood pudding, in which case they must first be cooked.

Sausage meats or meat mixtures which for some reason were dropped to the floor may not be used in any type of product.

Sausage meats made from comminuted and prepared meats not immediately used in sausage shall be kept under refrigeration at proper temperatures.

Article 138—Sausage manufacturers are not permitted to sell their products without the stamp affixed thereunto by the health inspection authority and the labels provided for in the present Code. Wholesalers and retailers shall keep stamps and labels on the product until they sell the last portion. Violators are liable to the established penalty and to summary seizure of the product.

Article 139—The term "fresh sausage" means sausage which, when exposed to ambient air, keeps from 24 hours (frankfurters) to 3 and 6 days ("butiferra," blood-pudding, fresh pork sausage).

The terms "preserved sausage" and "cooked sausage" mean sausages and similar products which have been subjected to a prolonged drying process in special dryers, have been preserved by salting, smoking, or condensed smoke, or have been subjected to cooking.

Cooked prepared meats are also designated by the generic name "cold cuts."

Article 140—The following generic names designate the products described hereinafter:

1. The term "matambre"* means the layer (strip) of meat between the skin and the rib case of cattle. The name "rolled matambre"

* Note of the Translator:
An Argentine beef product.

means beef "matambre" especially spiced, rolled, spirally tied with strong string, and cooked, first at low heat, then in boiling water. The name "minced matambre" means a cold cut prepared from beef "matambre," comminuted and mixed with other meats. It is usually cooked in pans and sold in cloth bags which stick to it because of the heat.

2. The generic name "Salami" designates various types of sausage prepared from a base of raw meat and aged, with bacon and spices added. Salamis are distinguished from each other by different names, depending on the grain size of the meat mixture, the seasonings, the process used in their preparation, their shape and size (Milan salami, Crespón, Ordinary or Criollo, Nostrale salami, etc.). They may be smoked or unsmoked.

3. The generic name "Pork sausage" ("chorizo") means various types of sausage prepared from pork, or from pork mixed with other food meats, with spices, and encased in the small intestine of calves (fine tripe), and tied at intervals of from 10 to 18 centimeters to form sausage strings, or tied into a varying number of links. These pork sausages are sold fresh or dried, smoked or unsmoked. They are distinguished by various names, depending upon their preparation (Spanish "chorizo," Oriental "chorizo," etc.). Brazilian "chouriços" usually contain a certain proportion of blood and pieces of entrails, heart, liver and tongue, and are sold cooked and smoked.

4. The name "salchicha fresca" (fresh sausage) designates a fresh sausage prepared from a mixture of beef, cheese, pepper, cinnamon, saltpetre and salt, filled into fine hog tripe without tying.

The names "Frankfurter" and "Wiener" mean sausages prepared with a mixture of beef and pork, dried milk, various sugars and spices. They are sold cooked and smoked.

They may, prior to smoking, be tenderized with pineapple juice, and benzoic acid and benzoic acid salts may be added to them in a proportion of 1 per mil if declared in the labeling.

Average percentage composition: water, 50 to 65; protein, 10 to 16; fat, 12 to 35; ash, 1.7 to 3.8; phosphorus, 60 to 320 mg.

5. The name "Italian sausage" designates a sausage prepared from pork and beef, salt, saltpetre, garlic, and coriander or fennel seeds. The mixture, coarsely chopped, is encased in calf tripe. It is then air-dried or hardened.

6. The generic name "blood sausage" designates sausages prepared with the blood of freshly slaughtered animals or birds, the skin and tendinous parts of pig's heads, bacon and spices, with or without

the addition of other products (milk, brain, etc.) and cooked in boiling water. They are distinguished by different names, depending upon the composition of the mixture: Basque, Genovese (Berrodi), Catalan, Criolla, Asturian etc. blood sausage.

7. The names "Bologna," "Stuffed tongue," "Ojo de Dios," "Sopresata," "Galantina," "Mambre," "Chinesco" designate cold cuts, which means cooked sausages prepared with mixtures of fresh or other meats, in proportions always to be stated in the labeling. When the name of the product indicates the use of a specific meat, such as: Calf bologna, Turkey "Galantina," Rabbit "Mambre," etc., the product must contain the meat of the animal named in a proportion of not less than 25 percent, while the balance may be pork or beef.

Several of these cold cuts are cooked in special pans; others are wrapped in cloth bags which stick to them by the effect of the heat.

Article 141—The name "Headcheese" designates a sausage prepared in varying proportions with the tendinous parts of the heads of swine and cattle, and with spices. When cooked in pans, headcheese is usually wrapped in cloth bags. Otherwise, it is cooked inside a bag made of pig skin with some fat sticking to it, which forms its casing.

Article 142—The name "Stuffed Pig's Feet" ("Zampette") designates the cold cut prepared from pork and pig skin, beef and spices, all of which is, after blending, encased in a pig's foot and cooked in boiling water.

Article 143—The name "Cima Rellena" designates a type of cold cut prepared by stuffing a kind of bag made of meat from beef rib casing or beef belly with a mixture consisting of beaten eggs, green peas, vegetables, cheese, beef tongue, spices, and whole hard-boiled eggs, which, in the end, is cooked in boiling water.

When the stuffing contains gelatin of fowl (turkey, goose, chicken, etc.) the product is named: Turkey, Goose, Chicken "Cima."

Article 144—Canned meat preparations (sausages and similar products, precooked dishes, etc.) are not permitted to contain substances which reduce their nutritive value, are injurious to the health, or are prohibited by this Code or the health authorities.

Fishery Products

Article 145—The term "Fishery Products" covers fish, crustaceans, mollusks, batrachians (frogs), chelonians (turtles), and preserved products and preparations made from the same animals or parts of them. They must belong to edible species.

Article 146—Fish and shellfish canneries, as all establishments engaged in the processing of fishery products, shall meet the following requirements in addition to the general standards:

1. The rooms in which the raw product (fish, crustaceans, mollusks) is received and cleaned shall be furnished with drainage tables, basins and suitable pressurized water taps which permit the use of water in any quantity required; the containers used to ship the raw product to the plant may not be used for any goods other than fishery products, shall be maintained in good sanitary condition and shall be cleaned as soon as they have been emptied.

2. Both the aforesaid rooms and the rooms in which products are processed and packed shall have waterproof floors with a gradient to drainage. The drainage pipes shall have a siphon and be connected with a septic tank that communicates with the sewer. The walls up to 1.80 m. from the floor must be covered with a waterproof material; the tubs or barrels in which fish is left to stand to allow the salt to penetrate shall be easily cleanable; no petroleum cans, lubricating-oil drums or containers originally used for substances not suitable for human consumption may be used for the purpose. When salting takes place directly in the barrels or cans, they shall be kept at a suitable place distant from passageways. All machinery, implements and utensils in use shall be kept in good condition and shall be cleaned as often as necessary during the day. The oil that collects in canning machines during processing is prohibited from being used.

3. All cannery departments shall be removed from and not connected with sleeping quarters, and their inside and outside openings shall be protected by metal or plastic screens.

4. All canneries shall have tanks of sufficient size, with a waterproof lining, set up at a distance of not less than 20 meters from the processing rooms, in which solid canning residue shall be collected to be removed periodically. These tanks shall be easily cleanable and protected from insects and shall not constitute a nuisance or danger to the neighborhood.

5. Fishery products are prohibited from being processed commercially at plants located in areas other than fishing grounds unless the raw material is, with the approval of the health authority, shipped in brine or frozen immediately after capture and kept frozen until its arrival at the plant.

Article 147—All containers used for fishery products shall meet the requirements of this Code, shall be approved by the health authorities, and, in addition, shall have a labeling including the place of processing.

New wooden cases may be used to pack frozen, salted and dried (cod type) and smoked fish intended for the market, provided that they are lined with waterproof paper.

Canned fishery products shall after processing be kept under observation for six days for biological tests. No swelling shall occur on containers kept 48 hours in an oven set at 38° C.

When canned fish is labeled "with" or "in olive oil," the oil present in the tin may not contain fish oil in a proportion of more than 10 grams per 100 grams of olive oil.

Article 148—Brines used for salting shall be replaced or replenished as often as necessary and shall be prepared from potable water and virgin salt suitable for human consumption, as provided for in this Code, the addition of colors or preservatives, brick powder, ochres, etc. and the use of salt recovered from used brines being prohibited. They shall not have an iodine absorption of more than 1.2 grams per liter. Brines intended for the preparation of caviar may contain benzoic acid, benzoic acid salts, or hexamethylenetetramine, but any residue of these agents found in the product ready for sale is not permitted to exceed 1 per mil.

Article 149—Fish and shellfish pastes (from anchovies, sardines, shrimps, etc.) may be prepared only in canneries, their preparation in luncheonettes, tea rooms or similar establishments being prohibited.

Wheat, corn, potato or tapioca flour may be added to fish and shellfish pastes in a proportion of up to 20 percent and salt in a proportion of not more than 18 percent without declaring their presence in the labeling.

Article 150—Depending upon their nature and the process used to preserve them, fishery products are classified in the following types:

1. The name "salted fish" means fish preserved with edible salt in the form of solid salt or brine. Dried salted fish (grayfish, haddock, etc.) offered for sale may not contain salt (sodium chloride) in a proportion of more than 30 percent.

2. Salted or unsalted dried fish must have its natural color and may not be reddish or greenish. The moisture content of fish dried without brine shall not exceed 12 percent.

3. The name "stockfish" means a large fish (cod, haddock, hake, etc.) which, after cleaning, is dried without flattening or salting.

4. The name "Smoked fish" means fish subjected to the action of condensed smoke, after partial or total drying or salting (See Article 119). As an exception to Article 692,* these products may contain free or combined formol in a proportion of not more than 1,000 p.p.m. (in the dry residue).

5. The name "Broiled (or baked) fish" means fish which has been exposed to the action of fire or heated air in an oven.

6. The name "Marinated fish" (or "fish à la Bismarck") means fish which, after cooking, is preserved in flavored vinegar, with or without the addition of oil.

7. The name "Dried Shrimps" means fresh shrimps which have been cleaned, salted, and dried in the sun or in special ovens.

8. Cured anchovies put on the market must have been standing in brine for at least five months. When a can is opened it shall not smell of fermentation, shall not contain swollen anchovies or fat floating in the brine, and no fat may be found on the can edges or inside the lid. The salt used in canning shall meet the specifications fixed in this Code and may not be present in a proportion of more than 35 grams per 100 grams of product.

When an anchovy is split, its inside shall be a bright pink throughout (meat color) and shall have no lighter or whitish parts.

Anchovies in brine which are sold as "select," "fancy," "special," or under a similar designation, shall be of uniform size, not broken or split, and perfectly scaled; their heads must have been removed neatly and their skin must be intact. The can may not contain salt in a proportion exceeding 30 grams per 100 grams of product.

The term "meat anchovies" may only be used for anchovies packed tightly in brine the one on top of the other, without any layer

* Note of the Translator:
This article prohibits the addition of formaldehyde to foods.

of salt between them. The can may not contain salt in a proportion of more than 20 grams per 100 grams of product.

Anchovies intended for fillets must be allowed to mature in brine for not less than eight months.

Article 151—The names under which canned fish, mollusks and crustaceans are sold shall meet the specifications in force in their country of origin. Consideration shall be given to both the vernacular and the scientific names, as specified in Article 105.

Article 152—The term "Jellied fish" means the product made from fish boiled in a flavored broth, to which edible gelatin was added during packing.

Article 153—The term "Bouillabaisse" means a soup made from various types of fish and shellfish cooked together and spiced.

Article 154—The term "Caviar" means a preparation made from the salted roe of various species of sturgeon. In fresh or granulated caviar (Ikra,* körniger Kaviar**), which is grey in color, the eggs must stick to each other tightly; it shall contain water in a proportion of not more than 55 percent, fatty substances in a proportion of not more than 18 percent and total nitrogen substances in a proportion of not less than 23 percent. Pressed caviar ("Pajusmaya,"* "Presskaviar"**), which is dark grey or black and has the appearance of a solid oily mass, shall contain water in a proportion of not more than 35 percent and total nitrogen substances in a proportion of not less than 33 percent. It may not contain oil or roe of other fish. The protecting agents which may be used in its preservation (see Article 686) may be added in the form of a saline mixture containing, for instance: 94 parts of sodium chloride, 3 parts of hexamethylenetetramine and 3 parts of sodium benzoate.

Caviars made from the roe of other fish shall bear the name of said fish, such as Carp Caviar or Red Caviar, Haddock Caviar, Hake Caviar, etc., or the name ". . . . Caviar," preceded by the technical name of the fish whose roe was used in its preparation.

* Note of the Translator: Russian term. ** Note of the Translator: German term.

Regardless of the name under which caviar is sold (fresh or granulated, or pressed) and whatever its origin (genuine or substitute), it may not contain more than 10 percent of salt, more than 4.5 percent of free fatty acids expressed as oleic acid, and their content in nitrogen titratable in formol (Sörensen) may not exceed 0.05 grams per centum. It shall not have a free hydrogen sulfide reaction. Average percentage composition: Granulated sturgeon caviar: water, 48; protein, 27; fat, 15; ash (sodium chloride 6) 7.5. Pressed sturgeon caviar: water, 37; protein, 32; fat, 18; ash (sodium chloride 4) 5.5. Red Carp Caviar: water, 45; protein, 27; fat, 18; ash (sodium chloride 1.5), 4. Haddock Caviar: water, 50; protein, 23; fat, 12; ash (sodium chloride 8) 11.

Article 155—The term "Shark Fins" is used to distinguish the fins of selachians which are salted, or dusted with lime, and dried in the sun or in ovens, and are used mainly in the preparation of soups. Shark fins are classified into white and black, although none are perfectly white or black, and the following commercial types are known: Speckled white Fins (Boon Leong sit), which may be large (Chu sit), or small (Peh sit, and Khian sit), and Black Fins, which may be large (Tut sit), or small (Oh sit, or Seow oh sit).

Article 156—The following names are used to designate the products described hereinafter:

Bückling: smoked herring.

Haddock*: a large, salted, boned or unboned fish (cod, haddock, hake, bluefish, etc.) split and smoked.

Klipfish: a large fish (cod, haddock, hake, etc.) salted and dried.

Stockfish: a large fish (cod, haddock, hake, etc.), dried without salt, which is sold rolled or twisted.

Rollmops: strips of spiced marinated fish which are sold rolled.

"Saracas": pressed salted sardines or anchovies. **[The End]**

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* Note of the Translator:
This English name of a species of fish is apparently used in Latin America to designate a type of smoked fish.

The Administrator's View

By JAMES L. GODDARD, M.D.

Dr. Goddard, the Commissioner of Food and Drugs, Delivered This Address the Evening of July 28, 1967, at the Annual Convention of the Federal Bar Association, in San Francisco, California.

I AM DELIGHTED TO HAVE THIS OPPORTUNITY to share with you a view of the law that is peculiar to an administrator. The law and the regulations are those that fall within the jurisdiction of the Food and Drug Administration (FDA), which is celebrating its 60th anniversary this year.

Actually, I have the responsibility for enforcement of the Food, Drug and Cosmetic Act, with its many Amendments, and other Acts of the Congress that give us certain responsibilities in the marketplace. As you know, the daily traffic in our Agency is divided among foods, drugs, cosmetics, and hazardous substances. It has been estimated that no less than 25 cents of every consumer dollar spent buys a commodity over which we have some jurisdiction. There are times when I think we have the whole dollar's worth to contend with, but that is thankfully not the case even though it may seem that way.

However, I realize the extent of our influence on the lives of our citizens. And I am awed by it.

Considering the extent of the FDA's influence, the position of its Commissioner is potentially very powerful. But I choose the word "potentially" with great care. For the power that could be mine, as an enforcer of the law, is not at all absolute. It is carefully—and properly—circumscribed. Although I have been charged now and then with being arbitrary and capricious, I do not believe such charges hold true. I make such a claim because it is frankly impossible to administer the law—to oversee the work of some 5,000 employees—to hold together the labors of 17 District Offices in major cities across the Nation—to plan and program for today's environment and for tomorrow's as well—it is just impossible to do this and be capricious or arbitrary.

Those must have been the good old days, the days of the club-swinging curmudgeon, whether he was in private industry or in government. But those days are gone. And I do believe it is just as well. Power can corrupt. What we are concerned with, as administrators of the FDA law, is the wise and restrained use of power. This is good administration, good executive practice, good decision-making. It is more than just the procedures of enforcement.

I think it is also appropriate to say that my accent on administration of the law, rather than on enforcement, stems from the kinds of problems we are currently faced with in the FDA or, rather, in the Nation. For example, in the area of foods, we have observed during the past year or two a rise in the significance of salmonella. This is a pesty little microorganism that produces stomach upsets, what is called "food poisoning," sometimes mistakenly diagnosed as "flu," but a microorganism that, nevertheless, can be extremely dangerous to the very young and the very old, whose resistance to such insults is low, and a nuisance of no mean proportions to all other age groups.

It has been estimated that, in 1966, up to one percent of our population, nearly two million Americans, suffered from attacks of salmonellosis. At the minimum, an attack lasted two days. In one computation I have seen, this has been compared to a loss of one-and-a half million workdays during the year. Whether we are speaking in terms of a worker's down-time or in terms of medical gravity, salmonella is one of our major challenges in the area of contamination-free food processing.

There are a number of legal routes we may follow to impress upon the food industry that salmonella is very bad news indeed. But from my viewpoint, our Agency must have other alternatives—some more swift, less punitive, more effective for public health—than the resort to the courts. We must move swiftly when salmonella is detected. But we should not, and cannot, move alone if we are to achieve the desired end: protection of the health of the consuming public.

At this point, we see some mechanisms appearing that give the administration of the Food, Drug and Cosmetic Act a new relevancy to the contemporary problems of public health. We see that industry can approach us, the Agency that regulates it, and join us in the exchange of scientific data concerning salmonellosis. We also see that preventive measures can be worked out in an atmosphere of service to the public, rather than under the somber gun of enforcement. Thus, the Grocery Manufacturers of America, the National Renderers Association, the American Dry Milk Institute, the baking industry, candy

manufacturers—these and many others are working with FDA District offices as well as with our headquarters group to get a tighter hold on the salmonella problem and with good management and good will reduce the problem to smaller proportions.

Workshops, seminars, scientific meetings, training aids for supervisory and manufacturing personnel and other tools are being developed for better administration. Of course, the laws, civil and criminal, are also instruments that may be called into play. But these are expressions of hostility, the Agency's and the industry's toward each other, when the real issue is the eradication of a public health hazard.

Food free of contamination is the goal of our Agency and of the many sectors of the food industry. Not all companies can or wish to comply. Not all share our concern. Not all reach for this goal. We have companies among us that do not conform to good industry standards, that do not maintain proper sanitary conditions, that do not maintain proper surveillance over the incoming raw materials and the finished products off the line, that do not train their personnel with any rationally organized programs, that, in a word, play fast and loose with the health of the consumer. For such companies, we move from the administrative mechanisms available to us and turn to the enforcement procedures.

I don't wish to dwell much longer on the food side of our work. I think we are making good progress with this industry, although many problems still remain. But the signs all point to a greater partnership of effort on a scientific basis between the FDA and food processors so that the consumer may be well served by his Government as well as by private enterprise.

The consumer is, of course, the person we must keep in mind as we carry out the law. His protection is the rationale for our agency; in his name was the law passed by the Congress. We have, however, no direct access to the consumer: we make contact through industry. We have noted how this can be done in the food area—by working with industry on a health problem affecting consumers. What about our protection of the consumer, as far as drugs are concerned?

Here, again, we have taken a long, hard look at the law and have tried to draw from it the administrative procedures that could bring about consumer or patient protection without constant resort to litigation. I think this past year we have come through, by trial and error as well as by calculated design, a number of procedures that make good administrative sense.

Pharmaceutical Advertising

One of our most publicized and, indeed, most pressing problems was in the field of pharmaceutical advertising. When you stop and consider the problem for a moment, you will see that today's physician must rely almost totally upon what a manufacturer claims for his drug product. Such claims are first found in the package insert that accompanies the prescription drug. "Found" is probably not the most appropriate term here, since there is much evidence that the insert never gets into the doctor's hands. So the claims are given in a variety of advertising media. These are under the jurisdiction of the FDA, spelled out in law and regulation since 1962.

The doctor reads the journal ads for information. He cannot corral several thousand subjects, administer a drug in a special regimen or test design for months or possibly years, and come to all the conclusions by himself. He doesn't have the money, time, facilities, or even the need to go through this. It is even ridiculous to contemplate the average prescribing physician replicating the R & D process behind the claims for any prescription drug.

This very need to rely on company representations of fact levies upon both the company and the FDA a heavy responsibility that, once again, legal procedures alone cannot satisfy. Other techniques of administration must be called into play.

Face-to-face discussions with errant companies have been the rule in my office for over a year. There have been a few disappointments, but on the whole I must say that these discussions have been fruitful and the advertising of prescription drugs is improving. Executives in the industry are getting the message. And the message is rather simple. If we can get better information to the prescribing physician without dragging each other into court, then let's try. We began with discussions and a sprinkling of seizures. There have been very few seizures lately. Companies have chosen the "Dear Doctor" letter as a way of straightening out the record for themselves and for their special professional audience. And we have rested our legal lance in the corner in many instances, choosing the dialogue with the company and their willingness and ability to do the job themselves as being more profitable to all concerned—especially the patient at the other end. Let us not forget him. The reason for our discussions at the top corporate levels, for turning from seizures to "Dear Doctor" letters and other forms of righting the wrong information, is to get the best, most informed medical opinion and practice at the bedside of the patient.

Some executives have called us "tough," "unreasonable," and so forth. Yet, they fail to see we do not have many alternatives. Once an infraction of drug advertising, or manufacture, or research is brought to our attention, we must pursue it, or be counted as derelict. The real issue is not that we actually do track down the infractions, of course we will do this; the issue to discuss is this: Do we move rigidly in the patterns of old or do we seek to find new ways of accomplishing the desired ends with a minimizing of friction and disruption and a maximizing of protection for the public? If the answer is that we are indeed opening up new administrative avenues that are effective, then I am satisfied that the FDA is responding well to the mandate given it by the Congress.

I am not condemning pharmaceutical advertising. Pharmaceutical advertising occupies a large and important place as an information source for the practicing physician. But it can fulfill this function properly only if it provides America's four hundred thousand doctors and pharmacists with information that is prompt, reliable, accurate, complete and unimpeachably honest.

The FDA is not trying to stifle creativity in advertising. We recognize that the competition of creativity is an essential part of our economy and that it has contributed much to our national wealth. Accordingly, we have drafted new regulations covering pharmaceutical advertising, regulations developed with the help and experience of the drug industry. They are now being circulated for comment, and we look forward hopefully to their observance when they go into effect.

Oddly enough, many of these regulations would have been unnecessary had the drug industry members chosen to live up to the code of advertising ethics to which they had previously subscribed. Again it was a case where industry leadership faltered. So much of the corrective action could have been taken by the companies themselves. But in the absence of self-regulation, Government regulation will have to be invoked.

In this regard, one of the quieter areas has been cosmetics. Our attention has not been turned away from cosmetics; but until recently, neither the industry nor our Agency has been able to sit down in shirtsleeve fashion and talk frankly about the problems confronting us. We have been in the courts, as you all know, but results of these cases are still inconclusive.

I do not believe the American consumer is willing to wait for our agency to raise its performance in this area. We must show our mettle

now. And the same is true for the manufacturers. The issue for both of us is simply the safety of the products involved. With new channels of communications opening up between the FDA and the personnel of the companies in this fascinating industry, I believe we all can acquit ourselves well enough to the consumer. But the consumer's patience may wear thin one of these days—the issue of safety may suddenly appear in the form of serious injuries and hospital reports. Then it will be too late. Preventive administrative practices would seem to be the order of the day now. And I am pleased to report that the responsible leaders in cosmetics and toiletries feel the same way.

I have said before that the FDA operates in an environment created by business and industry. Business and industry do not operate in an environment set by the FDA. But let me point out also that FDA has a duty imposed upon it by the Congress and I do not intend to compromise that obligation in any way. You, as members of the bar and officers of the court, can fully appreciate my position and my resolve.

I have frequently wished that the managements of food, drug and cosmetic companies and their advisors would pay closer attention to what Congress has decreed and make a real effort to conform to it. I have frequently wished that these firms would read the pages of history in which regulatory agencies have recorded their activities.

We are not calculatingly unreasonable. We do not issue any edicts without foundation. We do not take any summary action. We do not inflict undeserved penalties. We do not hold Star Chamber proceedings. We issue our regulations pursuant to the mandate of the law. We issue them after consultation with industry, after investigation and study by our own people, and after comment, reaction, and suggestions by the companies that will be affected, as well as by consumer groups. They bring to the conference table the experience of the marketplace.

That is the ideal situation. But regretfully, the ideal appears to be, in some cases, at least, poised uncertainly at an ever-receding horizon. Instead of operating in an atmosphere of mutual respect and willingness to cooperate, some firms still prefer to ignore us, to place obstacles in our path, and, at best, to perform as undisputed champions in foot-dragging.

Some events of the last year have disappointed me. Efforts to enlist industry's support in raising standards have, I confess, not been

as successful as we all might have hoped. Industry, which so frequently runs surveys so that it may better serve the public, does not always believe that the Congress and FDA have the same mission. So Food and Drug has taken the initiative. I assure you we will continue and we shall not falter.

I believe it was Spinoza who said, "Nature abhors a vacuum." As our society grows more and more complicated, it too abhors a vacuum in the conduct of its affairs. When those institutions of society which should properly move in to fill a vacuum fail to do so, then Government itself may fill the vacuum and establish a code of conduct designed to protect the public health and welfare. It is my responsibility to assure all our citizens that their health is being advanced.

As I said earlier, I prefer by far to carry out this responsibility with the active help and cooperation of the companies that produce our foods, our drugs, and our cosmetics. I prefer to do it by creative administration. It is only as a last resort that we go to court. But we have been in court before, and we shall be there again.

Our legal box-score, by the way, is excellent. In fiscal 1967, the FDA referred 1,500 civil and criminal cases to the Department of Justice. Of those that actually went to trial, it appears that the Government lost only a half dozen.

But I would consider the FDA record much more successful, much truer to the interests of the American people, if we could achieve respect for and adherence to our legislation and regulations without the necessity of making additions to a court's docket.

I would not want to conclude my remarks with the thought that I am trying to put any of you out of work. I am not. But I am sure you all appreciate that the public good will be more happily served through prompt and direct administrative action rather than through a long process where the statistics demonstrate pretty conclusively that the Government invariably wins. **[The End]**

Administrative Inspection of Health Facilities as Unreasonable Searches

By MAVEN J. MYERS, LL.B., PH.D.

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IN *SEE V. CITY OF SEATTLE*,[1] the United States Supreme Court recently concluded that:

[A]dministrative entry, without consent, upon the portions of commercial premises which are not open to the public may only be compelled through prosecution or physical force within the framework of a warrant procedure.[2]

Factory inspections authorized in the Federal Food, Drug and Cosmetic Act,[3] as well as inspections authorized by the Drug Abuse Control Amendments[4] and the Federal Narcotics Act[5] will be affected by this decision, as will inspections by state authorities charged with regulation of the production and distribution of drugs.[6]

The constitutional basis of the decision is the fourth amendment's guarantee that:

The right of the people to be secure in their persons, houses, papers and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.[7]

Through the due process clause,[8] the provisions of the fourth amendment have been made binding on state as well as federal officials.[9]

Presumptive or per se Unreasonableness

From the point of view of the inspector and the inspected, it is important to realize what the Court has said (or has failed to say). Assum-

[1] 87 S. Ct. 1737 (1967).

[2] *See v. City of Seattle*, 87 S. Ct. 1737 (1967).

[3] 21 U. S. C. § 374, Federal Food, Drug and Cosmetic Act, as amended, § 704.

[4] 21 U. S. C. A. § 360a(d) (1966 Supp.), 79 Stat. 229 (1965).

[5] 26 U. S. C. § 4773.

[6] For example, N. Y. Education Law § 6819.

[7] U. S. Const. amend. IV.

[8] U. S. Const. amend. XIV.

[9] *Mapp v. Ohio*, 367 U. S. 643 (1961).

ing that the person to be inspected has not consented to the inspection,[10] has the Court said that a search without a warrant is unreasonable per se? The Court prefaced its remarks in *See* with the observation that:

(A) search of private houses is *presumptively* unreasonable if conducted without a warrant. The businessman, like the occupant of a residence, has a constitutional right to go about his business free from unreasonable official entries upon his private commercial property.[11] (Emphasis added.)

If the Court by this statement meant only that there is a presumption of unreasonableness, it becomes crucial to determine what factors can overcome this presumption.

Carden[12] has advocated the proposition that a warrantless search is unreasonable per se:

Unless the fourth amendment language is arbitrarily mixed with hornbook conceptions of common law rules applicable to local law enforcement, it seems *too plain for debate* that when the federal government undertakes to lay hands on a citizen, enter his premises, or seize his property, it *must* invoke the warrant procedure.[13] (Emphasis added.)

Another commentator, while noting some exceptions, states that, "as a general rule, in order for a search to be reasonable, *i.e.* constitutional, the requirement of a search warrant must be satisfied."[14] Others contend merely that, "the courts have resisted police encroachment by making the validation of a warrantless search or seizure more onerous than the probable cause test, for obtaining a warrant."[15]

It will be observed that the fourth amendment not only guarantees freedom from unreasonable searches and seizures, but establishes standards for the issuance of warrants. Those in the unreasonable per se camp contend that this grouping of search and warrant, "declares the existence of a right to be *secure* from unreasonable searches . . . and then provides an *exclusive* method for initiating reasonable ones."[16] (Emphasis on "exclusive" added.)

On the other hand, the reasonable without warrant camp separates the search from the warrant clauses of the fourth amendment:

The test of reasonableness set forth in the first clause is two-fold: (1) there must be reasonable grounds to justify the intrusion and (2) the search or seizure must be executed in a reasonable manner. Where the search or seizure is authorized by

[10] *Zap v. United States*, 328 U. S. 624 (1946), rev'd on other grounds 330 U. S. 800 (1947).

[11] See footnote 2.

[12] Carden, "Federal Power to Seize and Search Without Warrant," 18 *Vanderbilt Law Review* 1, 1964.

[13] See footnote 12.

[14] "Note—Fourth Amendment Application to the Mass Welfare Search," 18 *Hastings Law Journal* 228, 1966.

[15] "Comment—Cause to Search and Seize," 26 *Louisiana Law Review* 802, 1966.

[16] Carden, note 12 above, at 26.

warrant the test of reasonable grounds to search accedes to the magistrate's finding of probable cause.[17]

The historical basis of our fourth amendment, as detailed by Fraenkel,[18] suggests as a minimum that the inclusion of search and warrant in the same amendment was not accidental:

By the time of Charles II . . . search warrants were issued in Star Chamber proceedings to find evidence among the papers of political suspects . . . . Under George III they became, in effect, authorizations to . . . arrest anyone and to search any house in order to apprehend the unnamed authors of the alleged libels. . . .[19]

Fraenkel then notes Lord Camden's opinion in *Entick v. Carrington*,[20] which he describes as "one of the landmarks of English liberty,"[21] condemning the general character of the warrants. On this side of the Atlantic, according to Fraenkel, writs of assistance were issued to suppress smuggling (and, by confiscating the smuggled goods, to help pay for the French and Indian War). Otis, who previously was the attorney general for the Massachusetts colony,

In a speech of great eloquence . . . questioned the power of Parliament to authorize such writs. The Court, almost persuaded, sent to England for advice, but pursuant to orders received from the ministers later issued the writs. Here was the beginning of that long course of repression that ended in the American Revolution.[22]

In spite of his perception of search and warrant as being historically related, Fraenkel is not willing to equate the "unreasonable" which modifies search and seizure with the absence of a warrant:

It is significant that the Amendment itself is in two parts—one which forbids "unreasonable searches," and the other which requires certain specific particulars to be observed before warrants may be issued. This prohibition against "unreasonable searches" must, therefore, have been intended to cover something other than the form of the warrant.[23]

It should be observed that the inclusion of search and warrant in the fourth amendment need not be construed as making a warrant a prerequisite to a search. The inclusion of both terms in the same amendment is probably indicative of a relationship, but not necessarily of a prerequisite. This is not the way our bill or rights was written. For example, the sixth amendment provides that, "In all criminal prosecutions, the accused shall enjoy the right to a speedy and public trial, by an impartial jury. . . ."[24]

If, as a matter of construction, the lack of a warrant makes a search unreasonable under the fourth amendment, then lack of an

[17] "Comment — Cause to Search and Seize," note 15 above.

[18] Fraenkel, "Concerning Searches and Seizures," 34 *Harvard Law Review* 361, 1921.

[19] See footnote 18.

[20] 19 How. St. Tri. 1029, 95 Eng. Rep. 807 (1765).

[21] Fraenkel, note 18 above.

[22] See footnote 18.

[23] See footnote 18.

[24] U. S. Const. amend. VI.

impartial jury is a denial of the speedy and public trial of the sixth amendment. The latter result is absurd. "Speedy and public trial" and "impartial jury" are not related directly to each other, but are related through the central concept of "fair trial." Similarly, the requirements for a warrant and the concept of unreasonable search are not necessarily directly related to each other, but are related through the central concept of "right of privacy."[25] Thus, based merely on placement in the same amendment, it is not necessary to conclude that lack of a warrant makes a search unreasonable per se.

The Court itself has either provided no answer or, what is worse, has provided a totally unsatisfactory answer. In *See,* the Court made the statement quoted above that "(A) search of private houses is presumptively unreasonable if conducted without a warrant."[26] The statement is clearly a dictum in this case, since *See* involved a commercial warehouse and not a private house. The holding of the case, however, appears to be an unqualified assertion that inspection of non-public parts of a commercial establishment are invalid per se without a warrant or consent:

> We therefore conclude that administrative entry, without consent, upon . . . commercial premises . . . not open to the public may only be compelled . . . within the framework of a warrant procedure.[27]

Later in the opinion, the Court frames its holdings in these terms:

> We hold only that the basic component of a reasonable search under the Fourth Amendment—that it not be enforced without a suitable warrant procedure—is applicable in this context, as in others, to business as well as residential premises.[28]

Thus, the only clue that the Court is not advocating a per se rule is in the form of dictum and relates directly only to residential, not commercial, premises.

On the same day that *See* was decided, the Court also decided *Camara,*[29] involving administrative inspection of a dwelling. In *Camara,* the Court implied in at least two parts that a search, without either a warrant or consent, is permissible in certain instances:

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[25] Central to the concept of a "right of privacy" are the fourth and fifth amendments. It is arguable that the fifth amendment's protection against self-incrimination limits consent searches which turn up evidence of crime. See, "Note—Consent Searches: A Reappraisal After *Miranda v. Arizona,*" 67 *Columbia Law Review* 130, 1967. *Boyd v. United States,* 116 U. S. 616 (1886), implied that the fourth and fifth amendments prohibit orders compelling the production of papers. Davis has observed that, "Subsequent history is largely one of escaping the effects of the *Boyd* dictum." Davis, "The Administrative Power of Investigation," 56 *Yale Law Review,* 1111, 1947.

[26] See footnote 2.

[27] See footnote 2.

[28] See footnote 2.

[29] *Camara v. Municipal Court of the City and County of San Francisco,* 87 S. Ct. 1727 (1967).

(E)xcept in certain carefully defined classes of cases, a search of private property without proper consent is "unreasonable" unless it has been authorized by a valid search warrant.[30]

and,

Since our holding emphasizes the controlling standard of reasonableness, nothing we say today is intended to foreclose prompt inspections, even without a warrant, that the law has traditionally upheld in emergency situations.[31]

Thus, in *Camara* the Court twice implies that some residential searches are valid without a warrant, and once in *See* observes that a residential search without a warrant is only presumptively invalid. Nowhere, however, has the Court intimated that a warrantless search of commercial premises may be valid without consent. The statements in *See* are unqualified in asserting that either a warrant or consent are essential.

One alternative is that the Court has not yet provided an answer. The second alternative is that the Court will permit some warrantless searches without consent for residential premises but not for commercial premises. If this latter alternative is the implication of *See* and *Camara*, the Court is extending greater protection to businesses than to individual citizens. Such a position would be inconsistent with the Court's previous positions in protecting individual citizens' rights more strongly under the Bill of Rights than those of corporations.[32] The Court implied in *See*, again by dictum, that there may be less protection against searches in the business community: "We do not in any way imply that business premises may not reasonably be inspected in *many more situations* than private homes. . . ."[33] (Emphasis added.)

Thus it seems reasonable to reject the premise that businesses have more protection under the fourth amendment than private citizens. The strong implication in *Camara*, and to a lesser extent in *See*, is that some residential searches are permissible without either consent or a warrant. Accepting this and the assumption that the protection of business premises is less than, or at least equal to, the protection of residences, one must conclude that the Court has not adopted a per se rule equating unreasonable search with lack of a warrant or consent.

The Reasonable Warrantless Search

The Court has previously sanctioned searches without a warrant where the search was incident to a lawful arrest. Thus, in *Agnello v. United States*[34] the Court stated:

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[30] See footnote 29.

[31] See footnote 29.

[32] For example, the Court has held that a corporation is not entitled to protection against self-incrimination under the fifth amendment. *Hale v. Henkel*, 201 U. S. 43, 76 (1906).

[33] See footnote 2.

[34] 269 U. S. 20 (1925).

The right without a search warrant contemporaneously to search persons lawfully arrested while committing crime and to search the place where the arrest is made in order to find and seize things connected with the crime as its fruits or as the means by which it was committed, as well as weapons and other things to effect an escape from custody, is not to be doubted.[35]

Mr. Justice Frankfurter's dissent in *United States v. Rabinowitz*[36] casts some doubt on the broad assertion in *Agnello*:

The short of it is that the right to search the place of arrest is an innovation based on confusion, without historic foundation, and made in the teeth of a historic protection against it.[37]

Although holding that the search in *Preston v. United States*[38] was unreasonable, Mr. Justice Black gave the following as one reason for allowing searches incident to an arrest:

The rule allowing contemporaneous searches is justified, for example, by the need to seize weapons and other things which might be used to assault an officer . . . .[39]

Yet, with all due respect for the safety of law enforcement officers, one may question whether the protection of the public health from the damages of unsafe drugs should not be of at least equal concern.[40]

Another exception existing "practically since the beginning of the Government"[41] is the

difference between a search of a . . . structure . . . and a search of a ship, motorboat, wagon or automobile . . . where it is not practicable to secure a warrant because the vehicle can be quickly moved out of the locality or jurisdiction in which the warrant must be sought.[42]

A third exception likely could occur upon the declaration of martial law.[43]

Running throughout these exceptions is the concept of an emergency situation—sufficient information to obtain a warrant likely is available, but by the time a warrant is obtained some great social wrong may have occurred.

Conversely, the Court has declared searches unlawful where a warrant could have been obtained. In *Johnson v. United States,*[44] a

[35] *Agnello v. United States,* 269 U. S. 20, 30 (1925).

[36] 339 U. S. 56, 68 (1950).

[37] *United States v. Rabinowitz,* 339 U. S. 56, 79 (1950) (dissent).

[38] 376 U. S. 364 (1964).

[39] *Preston v. United States,* 376 U. S. 364, 367 (1964).

[40] An excellent documentation of this need for protection is found in Stahl and Kuhn, "Inspections and the Fourth Amendment," II *University of Pittsburgh Law Review* 256, 1950.

[41] *Carroll v. United States,* 267 U. S. 132, 153 (1925).

[42] See footnote 41. The officer must, of course, have probable cause for the search.

[43] 93 C. J. S. *War & Nat'l Defense,* § 40, 1956.

[44] 333 U. S. 10 (1948).

police officer recognized the smell of burning opium coming from a hotel room. The sole occupant of the room was arrested[45] and the subsequent search was declared invalid. The Court noted that:

> At the time entry was demanded the officers were possessed of evidence which a magistrate might have found to be probable cause for issuing a search warrant.[46]

and that

> There are exceptional circumstances in which, on balancing the need for effective law enforcement against the right of privacy, it may be contended that a magistrate's warrant for search may be dispensed with . . . No reason is offered for not obtaining a search warrant except the inconvenience to the officers and some slight delay necessary to prepare papers and present the evidence to a magistrate. These are never very convincing reasons. . . .[47]

The Court made a similar observation in *Camara*:

> There was no emergency demanding immediate access; in fact, the inspectors made three trips to the building in an attempt to obtain appellant's consent to search. Yet no warant was obtained. . . .[48]

Another possible exception may be where criminal sanctions are not involved. In both *Camara*[49] (writ of prohibition sought to prevent criminal trial of Camara for refusing to allow inspector to enter) and *See*[50] (appeal from conviction for refusing to allow fire inspector to enter commercial premises) criminal sanctions were involved. *Camara,* however, rejects this on two grounds: first, it would be saying that suspected criminals are protected by the fourth amendment to a greater extent than law-abiding citizens and, second, that the only way to enforce the inspection process and obtain correction of deficiencies shown by the inspection is through criminal sanctions, either directly or indirectly.[51]

Another possible exception may be based on the importance of the public protection involved. For example, the harm created by a firm's failing to pay its employees a minimum wage likely is less than the harm that could result from a firm's wide distribution of a harmful drug. Thus, a search of wage records to determine the former question would appear less reasonable than a factory inspection to determine the latter. Davis suggests this theory is inapplicable in contemporary society. "The concept of business affected with a public interest has now disappeared from federal constitutional law.

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[45] The arrest was invalid because, prior to entering the room, the officers did not know whether there were one or several occupants.

[46] *Johnson v. United States,* 333 U. S. 10 (1948).

[47] See footnote 46.

[48] See footnote 29.

[49] See footnote 29.

[50] *See v. City of Seattle,* 87 S. Ct. 1737 (1967).

[51] See footnote 29.

. . . Accordingly, the cases which forbid investigations of businesses not affected with a public interest can no longer be controlling authority."[52]

In the particular relation of the Federal Food, Drug and Cosmetic Act to the public interest it has been observed that

> The cases show a tendency to rely upon "the police power" as a complete answer to challenge on search and seizure grounds, forgetting that the Search and Seizure Clause is a limit on the police power. However, these cases do stand as empirical recognitions that such inspections meet the test of "reasonableness." They seem to be based on the underlying assumption that when persons openly enter a business dealing with as sensitive a subject as the public's food or drug supply, the area of reasonableness of inspection of their affairs increases to coincide with the demands of efficient administrative supervision.[53]

Camara, however, indicates that the business affected with a public interest question does not bear on whether a warrantless, consentless search is unlawful, but rather on whether a warrant to search should be issued.[54]

Thus, emergency situations appear to be the only area in which warrantless searches are "reasonable" without consent. To the extent that such situations are more prevalent in drug law enforcement than in other legal areas, drug agents have more discretion in whether or not to obtain a warrant. The area of emergency searches is, however, very narrow and likely will be subjected to further limitations in the future.

Warrants

Thus, lacking consent or an emergency, a warrant is essential to a lawful search. The fourth amendment provides that:

> (N)o Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized.[55]

The major difficulty which *Camara* and *See* create, and attempt to overcome, is understanding what is probable cause.

Rule 41 of the Federal Rules of Criminal Procedure[56] provides for the issuance of warrants to search and seize property:

> (1) Stolen or embezzled in violation of the laws of the United States; or
>
> (2) Designed or intended for use or which is or has been used as the means of committing a criminal offense; or

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[52] Davis, "The Administrative Power of Investigation," 56 *Yale Law Review* 1111, 1947.

[53] "Developments in the Law—The Federal Food, Drug and Cosmetic Act," 67 *Harvard Law Review* 632, 1954.

[54] See footnote 29.

[55] U. S. Const. amend. IV.

[56] Fed. R. Crim. P. 41(b).

(3) Possessed . . . for use . . . in violation of Title 18, U. S. C. § 957 (Possession of property in aid of foreign government).

Neither of these three provisions can be construed as a grant of power to issue warrants for administrative inspection programs.

Traditionally, "probable cause" in the Constitution has been interpreted as meaning probable cause that a crime has been or will be committed.[57] After declaring in *Camara* that most administrative searches would require consent or a warrant, the Court gratuitously, and therefore, in dictum, propounded the following interpretation of probable cause:

> In determining whether a particular inspection is reasonable—and thus in determining whether there is probable cause to issue a warrant for that inspection—the need for the inspection must be weighed in terms of [the] . . . reasonable goals of code enforcement.[58]

However, in most cases there does not exist any statutory authority allowing the issuance of a warrant in these conditions.

As Christopher observed in 1953:

> It is . . . apparent that the requirement of probable cause and that of a description of the goods eliminate the possibility of the use of the search warrant in a large percentage of FDA inspections. There generally will be only suspicions or conclusions rather than facts.[59]

Thus, unless the Federal Rules are changed or the dictum of the Court is accepted as impliedly establishing new rules, drug inspections must be based either on consent or sufficient evidence of crime to come within the existing Federal Rules.

It has been observed that under the 1906 Federal Food and Drugs Act, which did not contain an inspection provision, voluntary inspectors had the cooperation of an estimated 95% of the factory owners approached.[60] Similarly, after the Court in 1952 declared the inspection provision of the 1938 law void, "most operators were still willing to permit factory inspection. The number of refusals, however, did increase sharply. . . ."[61]

It is interesting to note Christopher's comments on the present section 704:

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[57] For example, *Dumbra v. United States*, 268 U. S. 435 (1925).

[58] See footnote 29.

[59] Christopher, "Factory Inspection," 8 Food Drug Cosmetic Law Journal 101 (February, 1953).

[60] "Developments in the Law—The Federal Food, Drug and Cosmetic Act," note 53 above.

[61] *United States v. Cardiff*, 344 U. S. 174 (1952).

Involved is the inspection of a factory without any basis for suspicion of wrongdoing—merely looking around to see if a violation happens to exist. In ordinary criminal matters, of course, a search warrant would not issue in these circumstances. Much was made of this point in the debates in Congress and in the minority report in the House . . . with shadows of the old writs of assistance portended.[62]

Christopher's analysis indicates that the unreasonable search problem was an important consideration in the factory inspection provision:

Considering the importance of the factory inspection amendment . . . it is surprising that so much time was required to secure its enactment. . . . The main hindrance in the minds of the lawmakers appear to have been the constitutional questions, and the extent of the inspection to be allowed.[63]

The fourth amendment prohibits only "unreasonable" searches and seizures. In light of this, the factory inspection amendment provided for inspections, "at *reasonable* times and within *reasonable* limits and in a *reasonable* manner. . . ."[64] (Emphasis added.) As Hoge notes, "The repetition of the word reasonable is not a matter of redundancy, but of emphasis and of deference to the Constitutional guaranty against 'unreasonable searches and seizures.'"[65]

In spite of this, it is difficult to interpret *See* and *Camara* as allowing these inspections without either a warrant or consent.

Changing the Basis for Issuance of Warrants

Assuming that inspections are a necessary and proper ingredient in protecting the public health, some procedure is necessary to permit the efficient functioning of the inspection system. As was the case under the 1906 Federal Food and Drugs Act and following the invalidation of the inspection provision of the 1938 law, most inspections likely will be carried out with consent.

Two points are, however, apparent. First, assuming that someone who has something to hide will be less likely to consent to a search, a high incidence of consent searches is misleading as an enforcement criteria since it is likely that there is a larger proportion of violators among those who refuse consent. Second, consent is

[62] Christopher, "Significant Comments," 8 Food Drug Cosmetic Law Journal 600 (September, 1953).

[63] See footnote 62 at 600.

[64] 21 U. S. C. § 374, Federal Food, Drug and Cosmetic Act, as amended, § 704.

[65] Hoge, "Factory Inspection Under the Federal Food, Drug and Cosmetic Act (Section 704)" 21 Food Drug Cosmetic Law Journal 673 (December, 1966).

more likely to be given if the inspector has available an efficient method of authorization for a search without consent.

As has been observed, the warrant appears to be the only method for conducting a search without consent or an emergency. It also has been observed that the existing Federal Rules of Criminal Procedure do not authorize the issuance of a warrant for administrative inspections, absent a showing of probable cause that a crime is being, has been or will be committed.[66]

The Court stated, in effect, that probable cause for the issuance of a warrant will exist if the issuing officer finds that the "public need for effective enforcement"[67] of a regulation requires an inspection. It is suggested, however, that this dictum does not effect an immediate change in Rule 41 of the Federal Rules of Criminal Procedure which currently limits the authority to issue warrants.[68] Thus, one alternative to this predicament is a change in Rule 41. One commentator has framed the dilemma in the following terms:

> Were a showing of probable cause, in the traditional sense, required to secure authorization for these inspections, . . . health . . . authorities would necessarily have to wait until it might well be too late to prevent a health hazard from causing disease. . . . Relaxation of the standard of probable cause would be compelled by the need to avoid these consequences. But once the standard were relaxed, the routine issuance of warrants would compromise any effective protection against improper searches. . . .[69]

Thus, the principal concern involving a change in Rule 41 to permit administrative inspections is that by relaxing the standards for issuance of warrants, warrants will become so common that their issuance is likely to be reduced to a bureaucratic "rubber stamp" process.

One of the primary purposes for requiring a warrant is so the "decision to enter and inspect will not be the product of the un-

[66] § 301(f) of the Federal Food, Drug and Cosmetic Act makes it a misdemeanor to refuse to permit entry or inspection under the factory inspection provision (§ 704). Thus it could be argued that if an inspector is refused entry, a crime is committed, and a warrant could then be issued.

However, *See* and *Camara* both indicate the existence of a constitutional right to refuse entry to an inspector who does not possess a warrant. Since a provision making it a crime to refuse inspection negates this constitutional right, § 301(f) is, by implication, unconstitutional.

Therefore, violation of § 301(f) could not be used as a basis for probable cause that property "has been used as the means of committing a criminal offense" to support the issuance of a warrant under Rule 41 of the Federal Rules of Criminal Procedure.

[67] *See v. City of Seattle*, 87 S. Ct. 1737 (1967).

[68] Rule 41, however, does not apply in situations in which a specific statute provides independent grounds for the issuance of a warrant.

[69] "Comment — Administrative Inspections and the Fourth Amendment: A Rationale," 65 *Columbia Law Review* 288, 1965.

reviewed discretion of the enforcement officer in the field."[70] The danger in relaxing Rule 41 is that the issuance of a warrant may become such an automatic procedure that warrants may be issued without the issuing officer making an independent review of the necessity for the search. Were this to occur, it would defeat one of the principal purposes of requiring a warrant.[71]

Thus, any change in Rule 41 should be limited to what is necessary for efficient enforcement of reasonable standards to protect the public. Rule 41 should not be so narrow as to allow inspections only after public injury occurs nor so broad as to eliminate the protection which the warrant is designed to guard.

Consent

The protection of the fourth amendment can be waived.[72] Among the issues presented in consent searches are the authority of the person giving consent, whether the consent was given as an intentional relinquishment of a known right, and whether consent can be limited to inspection for specific purposes.[73]

As either an alternative to or a supplement for broadening Rule 41, statutory changes are conceivable in which consent to inspect is a prerequisite to carrying on activities related to public health. In *See,* the Court impliedly validated such procedures by saying, "We do not . . . question such accepted regulatory techniques as licensing programs which require inspections prior to operating a business or marketing a product."[74] Strictly interpreting this statement, it would, for example, allow a state board of pharmacy to inspect a pharmacy prior to issuing a permit for the pharmacy but it does not specifically allow subsequent inspections to determine whether the conditions existing when the permit was issued are maintained.

Such an interpretation is unreasonable. Once it is admitted that the conduct of certain businesses or the marketing of certain products can be done only with the permission of the state and that the state

[70] *See v. City of Seattle,* 87 S. Ct. 1737 (1967).

[71] The fourth amendment requires that a warrant particularly describe "the place to be searched, and the persons or things to be seized." Thus, a second purpose of a warrant is that it gives the person on whom it is served a description of the inspector's authority.

[72] *Zap v. United States,* 328 U. S. 624 (1946), rev'd on other grounds, 330 U. S. 800 (1947).

[73] In general, see "Note—Effective Consent to Search and Seizure," 113 *University of Pennsylvania Law Review* 260, 1964.

[74] See footnote 70.

has the right to make its permission conditional upon consent to a search to determine if reasonable standards have been complied with, there would appear to be no reason why the state's permission could not be conditionally granted upon a continuing consent. Initial compliance with reasonable standards is of little protection to the public unless there is assurance that maintenance of these standards will continue.

This alternative would, however, require several statutory changes.

Summary

Two recent decisions of the Supreme Court indicate that, absent consent or an emergency situation, administrative inspections are unconstitutional unless the inspector has secured a warrant. In spite of dictum by the Court, existing procedure does not provide for the issuance of a warrant for administrative inspections absent probable cause of criminal activity.

The alternatives which will permit the efficient enforcement of drug laws are expanding the scope of Rule 41 of the Federal Rules of Criminal Procedure or statutory changes requiring waiver of some fourth amendment rights as a condition precedent to engaging in activities related to the manufacture and distribution of drugs. Either alternative has the potential for weakening, rather than strengthening, the protection afforded by the fourth amendment.

The final answer rests on securing a balance between "The right of the people to be secure . . . against unreasonable searches . . . . ." and the responsibility of government to protect the public health, a responsibility implied by the constitutional charge to "promote the general welfare." As Stahl and Kuhn expressed it:

> Only blind adherence to the formalities of freedom would justify the denial to government of a power which assures the substance of a fuller life for its people.[75]

[The End]

[75] Stahl and Kuhn, "Inspections and the Fourth Amendment," 11 *University of Pittsburgh Law Review* 256, 1950.

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